S. Hrg. 104–783

H.R. 1271—THE FAMILY PRIVACY PROTECTION ACT OF 1995

BEFORE THE

COMMITTEE ON GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

ON

H.R. 1271

TO PROVIDE PROTECTION FOR FAMILY PRIVACY

NOVEMBER 9, 1995

Printed for the use of the Committee on Governmental Affairs

U.S. GOVERNMENT PRINTING OFFICE

20-957 CC WASHINGTON : 1997

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-054160-3

S. Hrg. 104–783

H.R. 1271—THE FAMILY PRIVACY PROTECTION ACT OF 1995

BEFORE THE

COMMITTEE ON GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

ON

H.R. 1271

TO PROVIDE PROTECTION FOR FAMILY PRIVACY

NOVEMBER 9, 1995

Printed for the use of the Committee on Governmental Affairs

U.S. GOVERNMENT PRINTING OFFICE

20–957 cc WASHINGTON : 1997

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-054160-3

COMMITTEE ON GOVERNMENTAL AFFAIRS

TED STEVENS, Alaska, *Chairman*

WILLIAM V. ROTH, JR., Delaware
WILLIAM S. COHEN, Maine
FRED THOMPSON, Tennessee
THAD COCHRAN, Mississippi
JOHN MCCAIN, Arizona
BOB SMITH, New Hampshire
HANK BROWN, Colorado

JOHN GLENN, Ohio
SAM NUNN, Georgia
CARL LEVIN, Michigan
DAVID PRYOR, Arkansas
JOSEPH I. LIEBERMAN, Connecticut
DANIEL K. AKAKA, Hawaii
BYRON L. DORGAN, North Dakota

Albert L. McDermott, *Staff Director*
Susanne T. Marshall, *Professional Staff*
Leonard Weiss, *Minority Staff Director*
Michal Sue Prosser, *Chief Clerk*

CONTENTS

Opening statements — Page

Senator Stevens 1

Prepared statement:

Senator Glenn with attached letters 65

WITNESSES

Thursday, November 9, 1995

Wade F. Horn, Ph.D., Director, National Fatherhood Initiative 2

Art Mathias, President, Christian Coalition of Alaska 6

Hon. Charles E. Grassley, U.S. Senator from the State of Iowa 14

Robert H. Knight, Director of Cultural Studies, Family Research Council 18

Matthew Hilton, J.D., Ph.D., Springville, Utah 23

Sally Katzen, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget 34

Felice J. Levine, Ph.D., Executive Officer, American Sociological Association .. 38

Lloyd D. Johnston, Ph.D., Research Scientist and Program Director, Survey Research Center, University of Michigan 48

Alphabetical List of Witnesses

Grassley, Hon. Charles E.:

Testimony 14

Prepared statement 16

Hilton, Matthew:

Testimony 23

Prepared statement with attachments 24

Horn, Wade F.:

Testimony 2

Prepared statement 4

Johnston, Lloyd D.:

Testimony 48

Prepared statement with attachments 49

Katzen, Sally:

Testimony 34

Prepared statement with attachments 36

Knight, Robert H.:

Testimony 18

Prepared statement 21

Levine, Felice J.:

Testimony 38

Prepared statement with attachments 40

Mathias, Art:

Testimony 6

Prepared statement with attachments 7

Page

APPENDIX

Text of H.R. 1271 61

Prepared statements:

Sue Rusche (with attachments) 55

Department of Health and Human Services 67

Andrew Fois, Assistant Attorney General, U.S. Department of Justice, Office of Legislative Affairs 77

Dr. Linda A. Teplin, Director, Psycholegal Studies Program, Professor, Department of Psychiatry, Northwestern University 79

Thomas J. Gleaton, Ed.D., President, PRIDE 81

Doug Hall, Senior Vice President, PRIDE 82

Shirley Igo, President for Legislation, National PTA 83

American Academy of Pediatrics 86

Questions and Responses for:

Wade F. Horn, the National Fatherhood Initiative, submitted by Senator Glenn 88

Art Mathias, Christian Coalition of Alaska, from Senator Levin 91

Robert H. Knight, Family Research Council, from Senator Stevens with attached article from *The Washington Post* dated July 19, 1991 92

Matthew Hilton from Senator Glenn 97

Sally Katzen from Senators Stevens, Glenn, and Levin with attachments 103

Felice J. Levine from Senator Glenn and Senator Levin 184

Lloyd D. Johnston from Senator Levin 195

H.R. 1271—THE FAMILY PRIVACY PROTECTION ACT OF 1995

THURSDAY, NOVEMBER 9, 1995

U.S. SENATE,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, D.C.

The Committee met, pursuant to notice, at 9:33 a.m., in Room SD–342, Dirksen Senate Office Building, Hon. Ted Stevens presiding.

Present: Senator Stevens.

OPENING STATEMENT OF SENATOR STEVENS

Senator STEVENS. Good morning. This morning we are going to have a hearing on H.R. 1271, the Family Privacy Protection Act,[1] which would expand to all Federal agencies and programs family privacy protections similar to those that have been applied to programs funded through the Department of Education. H.R. 1271 is derived from Title IV of the Contract with America, and the bill has been sent to us from the House, obviously, for prompt handling.

Several cases have been brought to the Committee's attention where someone in school, without any knowledge of the parent, has made a decision on behalf of a minor child. No government official, no school official, and no academic can be a surrogate in carrying out the responsibilities of a parent or guardian.

Specifically, this legislation requires prior written consent for surveys or questionnaires. We often hear reference to the fact that many of society's ills are a result of a breakdown in the family unit and the lack of parental participation in our children's lives. If we do not act to protect parental rights, we will see a continuing erosion of parental participation.

Today we are going to examine in depth, I hope, the distinction between informed consent and written consent. We have had a number of expert witnesses that have agreed to come forward, and I look forward to an interesting and informative discussion. We are going to participate with two panels today. Each witness is requested to limit oral testimony to 5 minutes each so there will be enough time for questions from the Committee Members. We ask that you give us your written statements. We will accept them and print them in the record if we print the record. Committee Members will be asked to limit their questions to each panel to not more than 10 minutes each.

[1] The bill appears in the Appendix on pages 61–64.

Now, unfortunately, I must tell you this is a very difficult time for the Senate. We have a markup in Commerce going on starting now, we have a defense conference that I am chairman of starting at 11:30, and we have a series of other problems that could interrupt this hearing. So if it is interrupted, I have to apologize to you. You see that all my colleagues are here with me and are supportive. They obviously were already where I should be. But I do want to proceed with this hearing because I want to get this bill out.

We have on the first panel Dr. Wade Horn, and then Art Mathias, Robert Knight, and Matthew Hilton. If you would come forward, please. And when Senator Grassley comes in, I am going to ask you to interrupt and let him make a statement. He is a principal sponsor here.

Dr. Wade Horn is the Director of the National Fatherhood Initiative. Art Mathias is the President of the Christian Coalition from my State of Alaska. Robert Knight is the Director of Cultural Studies for the Family Research Council. And Matthew Hilton is both a J.D. and a Ph.D.

We are happy to have you all here, gentlemen. I hope that you will proceed as I requested and limit your statements to 5 minutes. Hopefully, we will be able to get through both panels, have a good record, and be able to get a vote of the Committee here before the end of next week. So we appreciate it.

Mr. Horn, you are first. Dr. Horn. Pardon me.

TESTIMONY OF WADE F. HORN, PH.D., DIRECTOR, NATIONAL FATHERHOOD INITIATIVE

Dr. HORN. Thank you very much. My name is Wade Horn. I am the Director of the National Fatherhood Initiative and a child psychologist. I also formerly served as Commissioner for Children, Youth, and Families in the U.S. Department of Health and Human Services and was a presidential appointee to the National Commission on Children.

Throughout my career, I have been a producer of research, a consumer of research, and a funder of research, including research with children. And so I am very pleased to have been invited here to testify in support of H.R. 1271, the Family Privacy Protection Act.

Legally as well as ethically, some potential participants in survey or questionnaire research do not have the competence to give their informed consent. The issue arises with a variety of populations, including persons with mental retardation and severe mental illness. But it is especially salient when conducting surveys with or distributing questionnaires to children. Sound legal and ethical practice dictates that in such situations informed consent must be obtained from someone competent to make a judgment as to whether or not participation in that survey or questionnaire is in the best interests of the individual. In the case of children, that person is clearly the child's parent or legal guardian.

The reason why researchers themselves cannot determine whether or not children will participate in their survey or questionnaire is that researchers will naturally tend to overestimate the importance of their survey or questionnaire while underestimating the risk to the potential participant. Others, such as school authorities

or social workers or government agents, may have less of an investment in the survey or questionnaire, but still do not have the same commitment to the well-being of the individual child as does that child's parent. This does not mean that parents will always put the interests of their children above their own, but rather that parents are the most likely agents to do so.

The primary obligation when securing the participation of children in surveys or questionnaire is to provide the child's parents with sufficient information so as to allow the parent to make a reasoned judgment as to whether or not the child's participation in that survey or questionnaire is in the child's best interests. The best way to ensure that the child's parents have been adequately informed of the particulars of that survey or questionnaire and have provided their consent is to require prior written parental consent.

There are some who maintain that to require written parental consent is too burdensome on the investigator. But that is the point. Requiring investigators to obtain informed consent from research participants is meant to place a burden on the researcher. It is far too easy for the investigator to believe that what they are interested in researching is critically important and, hence, minimize considerations concerning the welfare of the potential participant.

To correct for this bias, science over the years has made it an ethical requirement that, except for cases of unobtrusive observations of naturally occurring behavior in anonymous settings, researchers should obtain the informed consent of research participants prior to conducting the research. For children, this means obtaining the consent of his or her parents or legal guardian.

Others are concerned that requiring written informed consent will increase the cost of the surveys and questionnaires. But the cost of the survey or questionnaire is not a concern of the potential participants. It is the concern of the investigator. As such, the cost of conducting the survey or distributing the questionnaire is simply irrelevant to the ethical requirement to fully inform the parent of the potential participant as to the purpose and particulars of the survey or questionnaire.

Finally, some argue that requiring prior written parental consent will result in less representative samples, and, in fact, this may be the case. But, again, such concerns are irrelevant to the ethical considerations. Researchers are not entitled to use children as research subjects or to override the right of parents to direct the upbringing of their children simply because they think their survey or questionnaire is important.

Researchers need to appreciate that it is parents, and not they or even the government, who are in the best position to determine what is in the best interests of their children.

It has been my experience as a researcher that parental consent is fairly easily obtained except in cases where the investigation comes into conflict with the sensibilities or closely held beliefs of the parent. If large numbers of parents decline to allow their child to participate in a particular project, I would suggest that the researcher examine whether the project is either insensitive or con-

trary to the prevailing community standards as to what is an acceptable undertaking.

Refusing to obtain prior parental consent is, I believe, a very shortsighted strategy. While it may result in a better and more representative sample in a particular study, such behavior on the part of researchers invariably fuels public suspicion as to what it is that researchers are up to with their children. Researchers need to understand that in a free society individuals have a right to not participate in someone else's project regardless of the good intentions of that undertaking. To do otherwise threatens the longer-term viability of research projects because of the suspicion and hostility it invariably generates in potential participants.

The Family Privacy Protection Act would ensure that parents retain maximum decisionmaking authority when it comes to directing the upbringing of the children. It would also help to protect families from unwarranted incursions by researchers or government into family life. I highly recommend its passage. Thank you.

[The prepared statement of Dr. Horn follows:]

PREPARED STATEMENT OF WADE F. HORN, PH.D.

My name is Wade F. Horn, Ph.D. I am a child psychologist and the Director of the National Fatherhood Initiative, an organization whose mission is to restore responsible and committed fatherhood as a national priority. I also currently serve on the National Commission on Childhood Disability, and am an adjunct faculty in the Public Policy Program at Georgetown University. Formerly, I served as Commissioner for Children, Youth and Families within the U.S. Department of Health and Human Services, and was a presidential appointee to the National Commission on Children. In my career, I have been a producer of research, a consumer of research and a funder of research, including research with children. I appear here today to testify in support of the H.R. 1271, the Family Privacy Protection Act of 1995.

Legally as well as ethically, some potential participants in survey or questionnaire research do not have the competence to give their informed consent. The issue arises with a variety of populations, including persons with mentally retardation and severe mental illness, but is especially salient when conducting surveys with or distributing questionnaires to children. Sound legal practice dictates that in such situations informed consent be obtained from someone competent to make a judgment as to whether or not participation in the survey or questionnaire is in the best interests of the individual. Sound ethical practice dictates that the person giving such consent be someone whose primary interest is the welfare of the potential participant. In the case of children, that person is clearly the child's parent(s) or legal guardian.

As pointed out in *Ethical Principles in the Conduct of Research with Human Participants* published by the American Psychological Association, the reason why researchers themselves should not determine whether or not children will participate in their survey or questionnaire is that researchers will naturally tend to overestimate the importance of their survey or questionnaire while underestimating the risk to the participant.[1] Others, such as school authorities or social workers, may have less personal investment in the survey or questionnaire, but still do not have the same commitment to the welfare of an individual child as does the child's parent(s). This does not mean that all parents will always put the interests of their children above their own, but rather to reflect the common wisdom that parents are the *most likely* agents to do so.

The primary obligation when securing the participation of children in surveys or questionnaires is to provide the child's parent(s) or legal guardian with sufficient information so as to allow the parent to make a reasoned judgment as to whether or not the child's participation is in their child's best interest. The best way to ensure that the child's parent(s) or legal guardian has been adequately informed of the particulars of the survey or questionnaire is to require that the information be conveyed both orally and in writing. The best way to ensure that the parent(s) or

[1] *Ethical Principles in the Conduct of Research with Human Participants.* Washington, D.C.: American Psychological Association, 1973, page 12.

legal guardian has, in fact, given their consent for the child's participation is to require that the consent be given in writing. Although in some circumstances oral agreements are as binding legally as written ones, written agreements carry greater force precisely because they provide a higher level of proof that an agreement was, in fact, entered into by the parties. The same is true for written consent for a child to participate in a survey or questionnaire.

There are some who maintain that to require written parental consent for a child to participate in surveys and questionnaires is too burdensome on the investigator, and will both increase the costs of conducting surveys with or administering questionnaires to children and decrease the representativeness of the sample. I will address each of these concerns in turn.

Requiring investigators to obtain informed consent from research participants is *meant* to place a burden on the researcher. It is far too easy for a researcher to believe that what they are interested in investigating is critically important and hence minimize considerations concerning the welfare of the potential participant. To correct for this bias, science has over the years made it an ethical requirement that, except for cases of unobtrusive observations of naturally-occurring behavior in anonymous settings, researchers obtain the informed consent of research participants prior to conducting the research. Thus, the fact that obtaining consent may be perceived as burdensome to the researcher is *irrelevant* to the ethical requirement to ensure that potential participants knowingly provide their consent to participate after having been fully informed as to the potential risks and benefits. When children are involved, such obligations are even more paramount because children are generally not competent to provide informed consent themselves and must instead rely on someone else to determine whether or not participation is in their best interests.

The same reasoning applies to concerns about increasing the cost of surveys and questionnaires. The cost of the survey or questionnaire is not the concern of the potential participants. It is the concern of the researcher. As such, the cost of conducting the survey or distributing the questionnaire is simply *irrelevant* to the ethical requirement to fully inform the potential participant (or his or her parent(s) or legal guardian) as to the purpose and particulars of the survey or questionnaire.

Finally, some argue that requiring prior written parental consent will result in less representative samples. This may, in fact, be the case. But again, such concerns are *irrelevant* to the ethical considerations. Researchers are not entitled to use children as research subjects or to over ride the right of parents to direct the upbringing of their children simply because they believe their study is important. Indeed, the courts have long recognized that even the State does not have that right, absent evidence of imminent danger to the health and safety of the child. To suggest otherwise would, in effect, say that it is the researcher (or the state) and not the family who is primarily charged with rearing children and the agent most likely to be concerned with the welfare of the child.

Researchers need to appreciate that it is parents, and not they (or even the State for that matter), who are in the best position to determine what is in the best interests of their children. The bipartisan National Commission on Children understood this preeminent importance of parents and family when it wrote in it's final report:

> "Parents are the world's greatest experts on their own children. They are their children's first and most important caregivers, teachers, and providers. Parents are irreplaceable, and they should be respected and applauded by all parts of society for the work they do.[2]

President Clinton himself acknowledged this important reality when he stated during both his acceptance speech at the 1992 Democratic National Convention and a later State of the Union address that "Governments do not raise children—parents do".

If a particular researcher is unable to obtain an adequate sample after informing the potential participants of the purpose of the survey or questionnaire, it is likely that the survey or questionnaire is either insensitive or contrary to the prevailing community standards as to what is or is not an acceptable undertaking. It has been my experience as both a researcher and a supervisor of the research of others, that parental consent is fairly easily obtained except in cases where the investigation comes into conflict with the sensibilities or closely held beliefs of the parent. If large numbers of parents decline to allow the participation of their child in a given research project, I would suggest the researcher reexamine whether the project is sim-

[2] Final Report of the National Commission on Children, Beyond Rhetoric: A New Agenda for Children and Families, National Commission on Children: Washington, D.C., 1991.

ply too offensive to large numbers of individuals within that community to justify its undertaking.

Refusing to obtain prior parental consent before engaging children in research is at best a very short sighted strategy. While it may result in a better sample for a particular study, such behavior on the part of researchers invariably fuels public suspicion as to what it is that researchers are doing. Researchers need to understand that in a free society, individuals have a right to not participate in someone else's project regardless of the good intentions of that undertaking. To do otherwise, threatens the longer term viability of research projects because of the suspicion and hostility it inevitably helps to generate.

Despite my support for the Family and Privacy Protection Act, I nevertheless do have one suggested revision. I recommend that the Act make clear that the requirement for prior written parental consent for conducting surveys and questionnaires with children not be interpreted to preclude the examination and analysis of information routinely collected in federally-funded programs, provided those records have all identifying information removed. This situation is quite different from that in which an investigator is proposing to ask questions of children which are out of the ordinary routine of that program. Thus, examining school attendance records without personal identifiers would not require prior written parental permission since attendance is routinely collected in the schools. The same might be the case when examining participation rates in various federally funded programs. The requirement for prior, written parental consent should be reserved for situations in which the investigator is proposing to ask the child something that parents would not reasonably expect to be within the purposes of that federally funded program.

In summary, the Family Privacy and Protection Act would ensure that parents retain maximum decision making authority when it comes to directing the upbringing of their children. It would also help to protect families from unwarranted incursions by researchers or government into family life. I highly recommend its passage.

I thank you for the opportunity to provide you with this testimony in support of the Family Privacy and Protection Act of 1995.

Senator STEVENS. Thank you very much, Dr. Horn. I appreciate your brevity, too. Thank you.

Our next witness is Art Mathias. Art, nice to see you here. I appreciate you coming in from home to present testimony. Thank you.

TESTIMONY OF ART MATHIAS, PRESIDENT, CHRISTIAN COALITION OF ALASKA

Mr. MATHIAS. Thank you, Senator Stevens. Mr. Chairman, thank you for this opportunity to come and discuss with you folks today how the people of Alaska feel about such an important issue as the Family Privacy Protection Act. I am a father, a businessman, a concerned citizen, and the President of the Christian Coalition of Alaska.

After I was asked to testify last Thursday, I placed five phone calls to parents in Anchorage, Kenai, and Fairbanks. Since then my phone and fax have been ringing constantly, with the feelings and experiences of people in Alaska directed at our government because of its intrusions into their private lives and their families. I have never felt so much pain, anger, and frustration as these families have expressed. They feel violated, confused, and helpless. The government has usurped their rights and their responsibilities as parents. The government has said, in effect, you will raise your children our way.

One parent of a kindergarten student told me this story. The mother specifically requested to the principal that her daughter be excluded from the sex education class. Her request was not honored by the principal, and without the parents' knowledge or permission, the kindergartner was taught in graphic detail what a penis is, what a vagina is, what good and bad touching are. This is in a kindergarten class of boys and girls.

Another parent called and told me this horror story how her 16-year-old daughter was removed from her home and placed in foster care because premarital sex was not allowed in that home. The school nurse and counselor completely undermined the beliefs of that family.

I could go on with stories like these about intrusions into our families forever. But they are not related directly to H.R. 1271.

I would like to read to you a written testimony given to me by Lorraine Ferrell:

My name is Lorraine Ferrell. I am a resident of Anchorage, Alaska, and a member of the Anchorage School Board. My experience during the first 2 months of this current school year illustrates that H.R. 1271 is needed. One of the types of information that require parental consent in H.R. 1271 is political affiliations or beliefs. Please refer to the attached survey given in my son's social studies class entitled "Are You a Conservative or a Liberal?" After reading the statements on this survey, it becomes quite apparent that the political beliefs of a 13-year-old boy and his parents could easily be ascertained. Statement 13 states, "There should be a constitutional amendment against abortion." Most certainly this does concern the pupil's religious beliefs.

In addition to this survey, my 8th grade son has also taken a communication styles survey in his language arts class. I did not want my son to take either of these surveys, and my permission was not sought prior to his taking them. Supposedly, the purpose of this survey was to identify his learning style and determine his strengths and his weaknesses. My son reported the results back to me. He said, "Mom, the survey said I was anti-social, again." I must tell you my son has been subjected to these so-called learning style/self esteem surveys for the past 6 years. And how does it build his self-esteem when he is labeled "anti-social"?

If you put two and two together, you can see that my son is an independent thinking, opinionated young man who is not fitting into the "politically correct" mold of the Anchorage School District. And I am very proud of him and very frustrated as a parent that he has been subjected to these invasive surveys. If I, as a member of the Anchorage School Board, cannot protect my own son, who can? Please pass this much needed legislation and promulgate the regulations post haste. Thank you.

[The prepared statement of Mr. Mathias follows:]

PREPARED STATEMENT OF ART MATHIAS

Mr. Chairman, thank you for the opportunity to come before your Committee and discuss how the people of Alaska feel about such an important issue as The Family Privacy Protection Act. I am a father, a business man, a concerned citizen, and the President of the Christian Coalition of Alaska.

After I was asked to testify last Thursday I placed five phone calls to parents in Anchorage, Fairbanks, and Kenai. Since then my phone and fax have been ringing constantly, with the feelings and experiences of people in Alaska directed at our government because of its intrusions into their private lives and families. I have never felt so much pain, and anger, and frustration as these families expressed to me. They feel violated, confused, and helpless. The government has usurped their rights and responsibilities as parents. The government has said in effect that you will raise your children our way.

One parent of a kindergarten student told this story. The mother specifically requested to the principal that her daughter be excluded from the sex education class. Her request was not honored by the principal and without the parents knowledge

or permission, the kindergarten was taught what a penis is, what a vagina is, and what good and bad touching are. This is in kindergarten class of boys and girls!

Another parent called and told me a horror story of how her 16 year old daughter was removed from her home and placed in foster care because premarital sex was not allowed in their home. The school nurse and counselor had completely undermined the values and beliefs of their home.

I could go on and on with stories like these about the intrusions into private family matters. But they do not relate directly to H.R. 1271. I want to read to you written testimony given to me by Lorraine Ferrell.

"My name is Lorraine Ferrell, I am a resident of Anchorage, Alaska and a member of the Anchorage School Board. My experience during the first two months of the current school year (95–96) illustrates that H.R. 1271 is needed. The types of information that require parental permission are listed in Sec. 2 (a)(1) through (7) of H.R. 1271. One of the areas listed is parental political affiliations or beliefs. Please refer to the attached survey given in my son's social studies class entitled 'Are You a Conservative or a Liberal?' After reading the statements on this survey, it becomes quite apparent that the political beliefs of a 13 year old boy and his parents could easily be ascertained. Statement 13 states 'There should be a constitutional amendment against abortion.' Most certainly this concerns the pupil's religious beliefs as outlined in Sec. 2 (a)(7) of H.R. 1271.

"In addition to the 'Are you Conservative or Liberal?' survey, my 8th grade son has taken a communication styles survey in his language arts class. I did not want my son to take either of these surveys and my permission was not sought prior to his taking them. Supposedly the purpose of this survey was to identify his learning style and determine his strengths and weaknesses. My son has reported the results to me. He said, 'Mom, the survey said I was anti-social, again.' I must tell you my son has been subjected to these so called 'learning style/self-esteem' surveys for the past 6 years. How does it build his self-esteem when he is labeled 'anti-social'?

"If you put 2 and 2 together, you can see that my son is an independent thinking, opinionated young man who is not fitting into the 'politically correct' mold of the Anchorage School District. I am very proud of him and very frustrated as a parent that he has been subjected to these invasive surveys. If I, as a member of the Anchorage School Board, cannot protect my own son, who can? Please pass this much needed legislation and promulgate the regulations post haste. Thank you."

There are 2 points that I want to draw from these experiences. First, H.R. 1271 does not go far enough. In reading the legislative history that was included in the Committee report it is very clear where the courts stand. It is also very clear where our constitution, specifically the 10th amendment, stands. All of the rights and responsibilities in raising our children belong with the parents. And this is an area that the 10th amendment specifically requires that the Federal Government stay out of. But, the Division of Family and Youth Services agency in Alaska and in other states under Federal guide lines are terrorizing American families. The Federal Department of Education does anything but educate. Since this department was formed under the Carter Administration test scores have only decreased. Less than 50 percent of its $33 billion budget actually reaches the classroom. The Federal curriculum dictates are onerous. The Federal Department of Education needs to be eliminated.

The second point is that all of the laws in the world are of little value when the agencies ignore or find ways to "legally" violate them. The two surveys given to Lorraine Ferrell's son were given this fall, (copies enclosed) after the passage of Senator Grassley's "Parental Rights Restoration Amendment to Goals 2000" on March 31, 1994. These surveys have been given all across Alaska after the Department of Education was told by Federal law not too. Agencies are thumbing their noses at Congress. Additionally, Alaska law also specifically requires written permission from the student's parent or guardian. (copy enclosed) The American people are justifiably very cynical. If the vice president of the Anchorage School Board cannot get her wishes honored who can?

Mr. Chairman, our families are our most important asset. There is a saying "As the family goes, so goes the Nation." Our families are in trouble and so is our Nation. America is engaged in a fierce battle, some call it a second civil war. A civil war for the hearts and minds of our children and our grandchildren. Every level of government seems to think they know how to raise our children better than the parent does. Families are being attacked from many directions. We applaud the Contract For America in its pledge to strengthen our families.

I want to close with this quote from President Truman, "The basis of our Bill of Rights comes from the teachings we get from Exodus and Saint Matthew, from Isaiah and Saint Paul. If we do not have a proper fundamental moral background, we will end up with a totalitarian government which does not believe in rights for any-

body except the State." This is where we are at today. And it is happening on your watch. H.R. 1271 is an important first step. Thank you.

PREPARED STATEMENT OF LORRAINE FERRELL SUBMITTED BY MR. MATHIAS

My name is Lorraine Ferrell, I am a resident of Anchorage, Alaska, a parent of two teenage children and the vice-president of the Anchorage School Board. I wish to personally thank Senator Grassley for the provision in the Goals 2000 bill which prohibits requiring pupils to participate in certain tests and surveys without written parental consent. It is my opinion that the Anchorage School District has violated the provisions of the protection of Pupil Rights—20 U.S. Code 1232h as amended by the Parents Rights Restoration Amendment in Goals 2000 passed March 31, 1994.

In the Spring of 1995 a Student Risk Behavior Survey was administered in the Anchorage School District without obtaining the written consent of students who were adults or emancipated minors or parents of minor students. Attached is a copy of the survey. It is evident that this survey meets the criteria outlined in Sec. 439 (b) (3) and (4) as requiring parental written consent prior to administration. A similar survey was given to Fairbanks students. A copy of this survey is attached. It is evident that regulations need to be promulgated to put some teeth into the law that was passed in March 1994.

Testimony:

My name is Lorraine Ferrell, I am a resident of Anchorage, Alaska and a member of the Anchorage School Board. My experience during the first two months of the current school year (95–96) illustrates that a law like H.R. 1271 is needed. The types of information that require parental permission are listed in Sec. 2 (a)(1) through (7) H.R. 1271. One of the areas listed is parental political affiliations or beliefs. Please refer to the attached survey given in my son's Social Studies class entitled "Are You Conservative or Liberal?" After reading the statements on this survey, it becomes quite apparent that the political beliefs of a 13 yr. old boy and his parents could easily be ascertained. Statement 13 states "There should be a constitutional amendment against abortion." Most certainly this concerns the pupil's religious belief as outlined in Sec. 2 (a)(7) H.R. 1271.

In addition to the "Are You Conservative or Liberal?" survey, my 8th grade son has taken an communications styles survey in his Language Arts class. I did not want my son to take either of these surveys and my permission was not sought prior to his taking them. Supposedly the purpose of this survey was to identify his learning style and determine his strength and weaknesses. My son, reported the results to me. He said, "Mom, the attitude survey said I was anti-social, again." I must tell you my son has been subjected to these so called "learning style/self-esteem" surveys for the past 6 years. Please refer to the attached newspaper article where my frustration with such surveys was aired at an Anchorage School Board meeting in November 1993.

If you put 2 + 2 together, you can see that my son is an independent thinking, opinionated young man who is *not* fitting into the "politically correct" mold of the Anchorage School District. I am very proud of him and very frustrated as a parent that he has been subjected to these invasive surveys. If I, as a member of the Anchorage School Board, cannot protect my own son, who can? Please pass this much needed legislation and promulgate the regulations post haste. Thank you.

ATTACHMENT 1

§ 14.03.110 ALASKA STATUTES § 14.03.120

Sec. 14.03.110. Questionnaires and surveys administered in public schools. A school district, principal or other person in charge of a public school, or teacher in a public school may not administer or permit to be administered in a school a questionnaire or survey, whether anonymous or not, that inquires into private family affairs of the student not a matter of public record or subject to public observation unless written permission is obtained from the student's parent or guardian. (§ 1 Ch 23 SLA 1979)

Sec. 14.03.120. Education planning. (a) A district shall annually file with the department, and make available to the public, a report that:

(1) establishes district goals and priorities for improving education in the district;

(2) includes a plan for achieving district goals and priorities; and

(3) includes a means of measuring the achievement of district goals and priorities.

(b) The department shall summarize the reports submitted under (a) of this section as a statewide report, and provide a copy to the governor and to each member of the legislature.

(c) A district shall make efforts to encourage students, parents, teachers, and other members of the community to participate in the preparation of the report submitted under (a) of this section.

(d) Each public school shall, by May 31 of each year, prepare a report on the school's performance and the performance of the school's students. The report shall be presented to parents, students, and community members at a public meeting and forwarded to the chief school administrator of the district.

(e) A district shall, by October 31 of each year, provide to the State board, and make available to the public, a report on the performance of each public school and public school students in the district. The report must be entitled "School District Report Card To The Public" and must be prepared on a form prescribed by the department. The report must include:

(1) the percent of district students in the top and bottom quarter of standardized national achievement examinations; results under this paragraph shall be disclosed in a manner that does not reveal the individual identities of students;

(2) the percent of students who are not promoted to the next grade;

(3) student, parent, and community member comments on the school's performance;

(4) the annual percent change in enrollment and the percent of enrollment change due to student transfers into and out of the district;

(5) attendance, retention, and graduation rates; and

(6) the ways in which meaningful parent involvement in school performance was achieved.

Are You Conservative or Liberal?

How do you classify yourself on political issues? Are you conservative or liberal? Often these labels are used without understanding what they mean. These categories are applied in politics to the views and opinions people have about certain issues. The terms liberal or conservative should never be used as a personal insult but be firmly based upon issues. Deciding if you are a conservative or a liberal may not be as easy as it seems. Usually all issues have multiple aspects if they are analyzed. The better informed you are about all sides of an issue, the more likely you are to understand where you are on the political spectrum as well as to make sound decisions about political candidates.

There are certain attitudes and beliefs associated with each category. These are not rigid and unchanging. Conservatives today may want less government while conservatives two hundred years ago wanted more government. In applying these titles it is very useful to ask the question "conservative or liberal about what?" A person may be liberal about social issues but conservative regarding money. This brings us back again to the issues. The opinion you have about particular issues determines if you are a liberal or conservative. This is a list of issues. If you agree with the statement, check yes; if not, check no. If you do not know enough about the issue to have an opinion, mark the category Don't Know.

1. The schools should have voluntary prayer
2. The Equal Rights Amendment is needed
3. Relations with both Chinas (Taiwan and Communist) should be normalized
4. The States should bear more of the cost of welfare
5. We should have an arms agreement with Russia such as SALT II
6. There should be draft registration for all 19 year-olds
7. Public lands should not be made available for energy exploration
8. There should not be large cuts in personal income taxes
9. There should be a constitutional amendment to balance the budget
10. Nuclear energy plants should be closed
11. A big program to help unemployed youth should be passed by Congress
12. There should be a guaranteed minimum wage for everyone
13. There should be a constitutional amendment against abortion
14. The 55 mph speed-limit should be removed and left to each State to regulate

15. Teenagers should be employed at less than the minimum wage
16. Defense spending should be greatly increased
17. Funding for social programs such as education should be decreased
18. There should be a national health care program
19. Requirements for food stamps should be tightened
20. There should be a constitutional amendment to ban school busing
21. There should be no price controls on oil and gas
22. There should be a national child care program
23. Funding for the arts should come from individuals and businesses, not government
24. Scientific evolution should be taught in public schools
25. Conservation is the best method of energy production
26. High interest rates are a useful means of fighting inflation

---

ATTACHMENT 2

UNIVERSITY OF ALASKA ANCHORAGE,
3211 PROVIDENCE DRIVE, ANCHORAGE, ALASKA

DEPARTMENT OF EDUCATION

DR. VIRGINIA R. JOHNSON

ED. 601 STYLES: TEACHING AND LEARNING

COMMUNICATION STYLES SURVEY (CSS), MOK, PAUL

NAME _____ _____

STUDENT ID NUMBER _____ MALE
RACE Caucasian BIRTHDAY 00–00–00
DATE 10–30–95
RIGHT-HANDED

SCORES ____ ____ ____ ____
T F S I

Susan Sizelove Lyons
Wendler Junior High School,
2905 Lake Otis Parkway,
Anchorage Alaska

TLS STUDENT REPORT

Student Name: _____ _____

Boys (Grades 7–9)	Thinker	Feeler	Sensor	Intuitor
+2 SD	77.5	71.0	76.0	73.7
+1 SD	69.9	64.5	68.0	66.6
AVG.	62.3	58.0	60.0	59.5
–1 SD	54.7	51.5	52.0	52.4
–2 SD	47.1	45.0	44.0	45.3
SD	7.6	6.5	8.0	7.1

Based on N–590

Style Strengths:
Styles Needing Development:

ATTACHMENT 3

LEARNING STYLE PREFERENCE SURVEY

For each of the following statements mark them 4, 3, 2, 1, from the most (4) like you to the least (1) like you. Mark the one that is the most like you a 4, and the statement that is the least like you a 1.

1. I like to:
   read about people
   read short sports stories

read fantasy or science fiction stories
read about real events

2. I study best:
by myself without interruptions
by myself at the same time every day
with other people or in a group
in several short study sessions

3. I like to:
work fast and finish first
work carefully so I can get a good grade
talk with someone while I'm studying
think about an assignment before I do it

4. I like to:
be the leader in our group
think up ideas for our group
make sure we follow the instructions
help the others in our group

5. I want our group:
to get an A on the project
to have fun
to finish first
to do something different

6. I want to:
know exactly what to do and how to do it
figure out "how" by myself
have someone helping me work
be the group leader

Page 1 Total _____ _____ _____ _____

7. When I work on an activity or project I want:
to work with other students
to be neat and follow instructions
to have something to keep when I finish
to come up with different ideas

8. When I am given an assignment I want:
to work with a group of students
to know exactly how to do it
a project that doesn't take too long
want to think about it for awhile

9. When I talk with others I:
get bored when they talk too much
want to correct them when they are wrong
won't listen to the "same old thing"
want to talk about what I'm doing

10. When I can't do what I want to do I:
feel like someone doesn't like me
try to figure out why not
get angry
day dream a lot

11. Other people think that I am:
very talkative
neat and organized
a good leader
have a good imagination

12. When I have a writing assignment I:
have to think about it before I write it
want to know how it will be graded
want to write as little as possible
want someone to help me

13. When people don't agree with me I:
get my feelings hurt
tell them why I'm right
argue with them because I know I'm right
don't care and ignore them

Page 2 Total _____ _____ _____ _____

14. When I think of time, I:
like spending lots of time with people
manage my time very carefully

like to hurry and finish first
lose track of time when I'm thinking

15. When I meet new kids, I:
take my time getting to know them
let them come to me
find out what they like to do for fun
notice what they are wearing

16. When talking to kids I don't know, I want them to:
think that I am friendly
think I'm smart
think I'm a good leader
think I'm creative

17. When I'm nervous in front of others, I:
act silly
get "up-tight"
show-off
get confused

18. I feel happy when I:
get in a lot of activities
am liked by other kids
get good grades on my work
come up with new ideas

19. I can change other kids' minds when I:
talk them into it
prove that I'm right
can tell them "why"
can show them how

20. When everything goes wrong I:
try to get help
think it's my fault
get angry
want to be alone

Page 3 Total _____ _____ _____ _____

21. When others criticize me, I:
get my feelings hurt
get mad
get defensive
argue

22. When I have a problem, I want to:
find the quickest way to fix it
analyze the situation
find someone to help me with the problem
ignore the problem or daydream a solution

23. When talking about something I really like, I:
am specific and want to get it right
interrupt anyone who is talking
get excited and get new ideas as I talk
want everyone to understand what I mean

24. I think that sometimes I:
am too critical of myself
get involved in too many activities
am too friendly and trusting
have trouble finding the right words

Page 4 Total _____ _____ _____ _____

Page 1 Total _____ _____ _____ _____

Page 2 Total _____ _____ _____ _____

Page 3 Total _____ _____ _____ _____

Total T F S I

Name _____ _____ Date 1–30–95
School Wendler Jr. High Culture/Race ____
Birthday: Month ____ Day ____ Year ____
What hand do you use to write? ____

V.R. Johnson 7/9/94

Senator STEVENS. Thank you, Art. I am sure there are some people going to comment on what are you doing down here all the way from Alaska to testify. I can assure you in the times that I have been here and sat way down there to start with, every Chairman went out of his way to make certain that someone from his home State came in and testified on important issues. So I appreciate you coming.

Now, gentlemen, let me interrupt you. Senator Grassley is here, and he is on his way to another hearing. So we have agreed to let him testify, if you will just stand by for a minute. Stay where you are. He and I have an old combative relationship, so we will get along.

Senator I am happy to see you here.

TESTIMONY OF HON. CHARLES E. GRASSLEY, A U.S. SENATOR FROM THE STATE OF IOWA

Senator GRASSLEY. Thank you. Thank you for the opportunity to come before your Committee to discuss an issue of great importance to me. I have worked on this issue on the floor of the Senate recently, and it is, of course, an issue that I think is very important to our Nation's families.

Last year, I sponsored an amendment intended to give greater privacy protection to the family in programs funded through the Department of Education. The amendment passed the Senate, Mr. Chairman, 93–0—there was a roll call—and became part of final law. H.R. 1271, the bill before you, is an expansion of that amendment to apply to all federally funded programs, not just education. I think this expansion is needed and welcome.

The bill before this Committee is particularly timely because on October 27 of this year, the Department of Education closed the comment period on the regulations drafted to implement my legislation that passed 93–0. I was extremely disappointed in those regulations because I believe they gut the intent of the law to protect children and families from privacy intrusions without prior written consent. If the Department is not going to implement the law according to the intent of the statute, then Congress simply must act again to accomplish the goal that we intended a year ago.

There are several excellent provisions in the bill before you that I want to commend, and then I would like to make a few suggestions on how to give greater clarity to H.R. 1271.

Now, going back to my amendment of last year, it was an amendment to the Goals 2000 bill. In my amendment, I referred to "students" where this bill refers to "minors." I think the reference to minors is better because it clarifies that application is not limited just to school settings. The Department of Education regulations limited the scope of my original amendment to school settings. The problem with this approach is that if a researcher wants to avoid written parental consent, arguably all he has to do is administer the survey outside school walls. This defeats the purpose of the protections, and I commend the language of H.R. 1271.

Another positive note in H.R. 1271 is that it says that a person may not "require or otherwise seek the response of a minor" without prior written parental consent. This is another area where I

was disappointed in the regulations that the Department of Education issued this fall on my amendment of a year ago.

My amendment was intended to address the issue of whether the child could make the decision. I thought I made clear that the decision was the parent's to make, not the child's. Unfortunately, the Department of Education has not read it that way. The Department leaves the decision to the child by calling the survey "voluntary."

Mr. Chairman, I view the issue of privacy revelations by children much as the courts have already addressed the school prayer issue.

The Supreme Court has held that because school is a compulsory atmosphere, a child should not be "required" to engage in a prayer which may compromise his personal or family convictions. According to the Court, a child cannot be placed in a situation where a school official leads a prayer and the child is told it is "voluntary" and he can participate or not participate according to his own convictions or feelings.

I believe this approach should shed light on how to deal with privacy-revealing surveys or questionnaires given to children. My amendment of a year ago said that a student shall not be "required" to submit to a survey. This language was based on the prayer analysis I just described.

The bottom line is that we should not place a child in a compulsory atmosphere in the position of having to determine what is private information and whether or not it ought to be revealed. These are adult decisions to make. That is why my amendment left the decision specifically and deliberately in the hands of the parents.

Unfortunately, this is the biggest flaw with the Department of Education's regulations on my original amendment. They simply leave the decision in the hands of the child. They say it is "voluntary." This defeats the intent of my amendment. While I made this clear in my letter to the Department concerning the regulations, I do not assume that they will change their regulations.

Because of my disappointment with the Department's regulations, I am pleased that the bill before you, H.R. 1271, says that a person cannot "require or otherwise seek the response of" a minor without prior written consent. "Prior" and "written" are important words. Since there was apparently some question left in my original language, I urge this Committee to protect this language in H.R. 1271.

Another important issue is that both my amendment last year and the act before us require explicit written parental consent before a survey in a federally funded program which reveals private information can be given to a child. Note that it does not exclude tests just because they are anonymous. Even in cases where there is no record of the child, the parent's consent is required if the other criteria are met.

It was with deliberate intent that I required written parental consent. It is not enough to get implied consent.

Implied consent works like this: A note might be sent home to the parent saying something like, "If you don't object in writing by a specific date, your child will be given some survey." What if the parents are out of town or for some other reason do not receive the notice before the given deadline? Their child is not protected. The

only way to guarantee that parents know what is going on is to require their specific written consent before the survey is given.

While I realize that the research community wants to drop the requirement for written consent, I urge this Committee to resist that temptation.

I understand that researchers are concerned that having to get written consent could cost a bit more or hurt their samples. While I appreciate these concerns, the real issue is: Whose child is this anyway? Does the child belong to the school or does he belong to the parent? A parent should be able to make the decision of whether his child is used for research purposes. Even the most noble of research projects must defer to the parent's right to protect and direct his own child. Any other decision is presumptuous, Mr. Chairman. It is arrogant, and I think we ought to resist that attitude.

On another point, because of the problems with the Department of Education's regulations, I would ask this Committee to strike Section 6 of H.R. 1271 so that the bill will apply to Department of Education's programs as well. When the language of H.R. 1271 was drafted in the House, we did not know the Education's regulations would be so devastating to the purpose of our amendment a year ago and contrary to what 93 Senators unanimously supported. Since they are, then I am prepared to try another avenue to provide the necessary protections.

Additionally, it is important that the language be as simple and clear as possible for all federally funded programs. The worst thing Congress could do would be to have one law for all education programs and another slightly different law for all other federally funded programs. I want to urge one simplified proposal that applies to all federally funded programs.

In the final analysis, if a survey, analysis, evaluation, or questionnaire reveals private information in any federally funded program, the parents must give specific written consent. Now, let me emphasize, without that specific written consent their child should not participate, and the law ought to say, "cannot participate."

I sent a letter to you, Mr. Chairman, outlining a few other technical comments concerning the language. I trust it will be helpful to you, and I thank the Committee for considering this issue, and specifically for considering H.R. 1271. Thank you very much.

[The prepared statement of Senator Grassley follows:]

PREPARED STATEMENT OF SENATOR GRASSLEY

Mr. Chairman, thank you for the opportunity to come before your Committee to discuss an issue of great importance to me and to our Nation's families. Last year, I sponsored an amendment intended to give greater privacy protection to the family in programs funded through the Department of Education. The amendment passed the Senate 93–0 and became part of the final law. H.R. 1271 is an expansion of that amendment to apply to *all* federally funded programs. This expansion is needed and welcomed.

The bill before this Committee is particularly timely because on October 27, the Department of Education closed the comment period on the regulations drafted to implement my amendment. I was extremely disappointed in those regulations because I believe they gut the intent of the law to protect children and families from privacy intrusions without prior written consent. If the Department is not going to implement the law according to the intent of the statute, then Congress simply must act again to accomplish the goal.

There are several excellent provisions of H.R. 1271 that I would like to commend and then I would like to make a few suggestions of how to give greater clarity to the bill.

My amendment to Goals 2000 referred to "students" where this bill refers to "minors." I think the reference to minors is better because it clarifies that application is not limited to school settings. The regulations limited the scope of my original amendment to school settings. The problem with this approach is that if a researcher wants to avoid written parental consent, arguably all he has to do is administer the survey outside the school walls. This defeats the purpose of the protections and I commend the language of H.R. 1271.

Another positive note in H.R. 1271 is that it says that a person may not "require or otherwise seek the response of a minor" without prior written parental consent. This is another area where I was disappointed in the regulations on my amendment.

My amendment was intended to address the issue of whether the child could make the decision. I thought I made clear that the decision was the parent's to make, not the child's. Unfortunately, the Department has not read it that way. The Department leaves the decision to the child by calling the survey "voluntary."

Mr. Chairman, I view the issue of privacy revelations by children much as the courts have addressed the school prayer decisions.

The Supreme Court has held that because school is a compulsory atmosphere, a child should not be required to engage in a prayer which may compromise his personal or family convictions. According to the court, a child cannot be placed in a situation where a school official leads a prayer and the child is told it is "voluntary" and he can participate or not participate according to his own convictions or feelings.

I believe this approach should shed light on how to deal with privacy-revealing surveys or questionnaires given to children. My amendment said that a student shall not be *required* to submit to a survey. This language was based on the prayer analysis I just described.

The bottom line is that we should not place a child in a compulsory atmosphere in the position of having to determine what is private information and whether to reveal it. These are adult decisions to make. That is why my amendment left the decision specifically and deliberately in the hands of parents.

Unfortunately, this is the biggest flaw with the Department of Education regulations on my original amendment. They simply leave the decision in the hands of the child. They say it is "voluntary." This defeats the intent of my amendment. While I made this clear in my letter to the Department concerning the regulations, I am not assuming they will change their regs.

Because of my disappointment with the Department's regulations, I am pleased that H.R. 1271 says that a person cannot require *or otherwise seek the response of a minor without prior written consent.* Since there was apparently some question left in my original language, I urge the Committee to protect this language in H.R. 1271.

Another important issue is that both my amendment last year and the act before us require *explicit written parental consent* before a survey in a federally funded program which reveals private information can be given to a child. Note that it does not exclude tests just because they are anonymous. Even in cases where there is no record of the child, the parent's consent is required if the other criteria are met.

It was with deliberate intent that I required *written* parental consent. It is not enough to get implied consent. Implied consent works like this: A note is sent home to the parent saying: "If you don't object in writing by a specific date, your child will be given this survey." What if the parents are out of town or for some other reason do not receive the notice before the given deadline? Their child is not protected. The only way to guarantee that parents know what is going on is to require their specific written consent *before the survey is given.*

While I realize that the research community wants to drop the requirement for written consent, I urge this Committee to resist that temptation.

I understand that researchers are concerned that having to get written consent could cost a bit more or hurt their samples. While I appreciate these concerns, the real issue is: Whose child is this anyway? A parent should be able to make the decision of whether his child is used for research purposes. Even the most noble of research projects must defer to the parent's right to protect and direct his own child. Any other decision is presumptuous and arrogant and must be resisted.

On another point, because of the problems with the Department of Education's regulations, I would ask this Committee to strike Section 6 of H.R. 1271 so that the bill will apply to Department of Education programs as well. When the language of H.R. 1271 was drafted in the House, we did not know the education regulations

would be so devastating to the purpose of my amendment. Since they are, I am prepared to try another avenue to provide the necessary protections.

Additionally, it is important that the language be as simple and clear as possible for *all federally funded programs.* The worst thing Congress could do would be to have one law for all education programs and another slightly different law for all other federally funded programs. I would urge one simplified proposal that applies to all federally funded programs.

In the final analysis, if a survey, analysis, evaluation, or questionnaire reveals private information in any federally funded program, the parents must give specific written consent. Without that specific written consent, their child cannot participate.

I sent a letter to you, Mr. Chairman, outlining other technical comments concerning the language. I trust it will be helpful to you and the Committee as you consider the act.

Senator STEVENS. Thank you, Senator. I am going to defer any questions, but we will review your letter, and I understand your request of the Committee with regard to Section 6. I think that makes eminent sense, so we will present that motion to the Committee to delete Section 6.

Senator GRASSLEY. Thank you very much.

Senator STEVENS. Have you checked over with the House as to what—that will slow down this bill. I would urge you to check with the House about that.

Senator GRASSLEY. Okay. Well, remember what I said. One of the reasons that it didn't deal with that is because maybe that had been taken care of with my amendment a year ago. And as I have indicated to you, we haven't.

I am not surprised by what the Department of Education did because, you see, we adopted it 93–0. Senator Ted Kennedy said he would fight for it in conference, and he did. He did fight for the Senate in the conference, and we got it. But behind the scenes, there were negotiations going on that would really gut it. But I got to Senator Kennedy and he short-circuited those efforts to gut it. So we got it through the way we wanted it. But then behind the scenes where the faceless bureaucrats are operating, then it can be undercut. And it was undercut. So I am not really surprised at what happened.

Senator STEVENS. Thank you very much. Gentlemen, we will proceed now.

Mr. Knight, could we have your statement please, sir?

TESTIMONY OF ROBERT H. KNIGHT, DIRECTOR OF CULTURAL STUDIES, FAMILY RESEARCH COUNCIL

Mr. KNIGHT. I am Robert H. Knight, Director of Cultural Studies at the Family Research Council. I am a former journalist, having been a news editor at the *Los Angeles Times*, a media fellow at the Hoover Institution at Stanford University, and a senior fellow for cultural policy studies at the Heritage Foundation.

We appreciate your including Family Research Council in this hearing, and we feel we are speaking on behalf of many parents all over the United States.

In the 1986 White House Working Group on the Family, the Final Report included these words: "Parental nurturing and education of the young is our most important national investment. It is the fundamental task of humanity."

Those words were penned by my boss, Gary Bauer, and nothing that has happened since has changed the truth of what he said. It could have been said at any time and any place.

We often hear from child rights advocates that it takes a whole village to raise a child, but parents are indispensable. Not even a whole village can replicate them. As the people most responsible for and most equipped to discern the needs of their children, parents must be accorded deference in all matters of education. Children in public and private schools are taught by dedicated professionals, but only because the parents consent to have these professionals participate in their education.

No one but a parent can understand how parents feel about their own children. And I am talking about adoptive parents as well as biological ones.

Mother Teresa described such devotion through a firsthand observation at her clinic in Calcutta. She said, "I never forget, I gave a child to a Hindu family, and after a few months, I heard that the child became very, very sick. And I sent for the family, and I told them, give me back that child. I'll take care of the sick child, and I'll give you another healthy child. And the father looked at me and said, 'Mother, take my life rather than take the child.'"

Like this Indian father, most parents would lay down their lives for their children. And they are acutely aware of this responsibility. So decisions about what kind of information is conveyed to children or extracted from them are the parents' natural prerogative.

Any research methods, including surveys, that place a barrier between children and their parents should be outlawed. Increasingly, parents have found themselves fighting for their most fundamental rights against hostile educators and government officials who honestly believe that they, not the parents, know what is best for the children. Such officials work overtime to acquaint children with revisionist history, graphic sexual materials, and relativistic notions of morality—all in the name of research and education.

Often, parents are unaware of what the children are receiving. The concept of informed consent is faulty because there are too many ways for it to fail, as Senator Grassley pointed out. Parents are often not given adequate information, and a teacher may send a child home with an announcement about an upcoming survey. But unless the parent signs a permission form, there is no way to determine if the parent ever got the message.

As a parent myself, I can tell you those messages don't always get through.

To those who argue that written requirements are cumbersome and expensive, the loss of parental freedom to determine a child's education is a far higher cost, one that is unacceptable.

There are other ways that information can be obtained on dangerous behaviors. Documentation of numbers of cases of out-of-wedlock pregnancies, sexually transmitted diseases, suicides, drug overdoses and the like is readily available. The drive to target all teens and children because of the actions of the unfortunate few is a manifestation of the educational dogma that information in and of itself, with no moral reference, can make a difference. But two decades of research have shown that giving youngsters more value-free information about sex, for instance, has not resulted in any be-

havioral change at all, except perhaps earlier experimentation, leading to more problems.

With the advent of Goals 2000, and its emphasis on national standards and accountability, the role of testing is becoming paramount. Outcome-based education, as implemented by Goals 2000, moves schools away from the strictly academic and toward the production of certain "attitudes." Consequently, the line is becoming blurred between what is educational and what is therapeutic.

Parents are worried about surveys for two reasons: Some questionnaires reveal information that is nobody's business but that of the family, and some questionnaires convey information to the children that the parents would rather their children were not exposed to.

The issue has been driven primarily by sex, suicide, and drug surveys among young teens, some of which have been politically motivated and manipulated. A few years ago, a national youth survey on sexuality contained questions that were so graphic that many parents felt they were pornographic.

Concern over research on hapless children has also been driven by revelations of abuses by federally funded researchers going as far back as the famous studies of Alfred Kinsey in the 1940's. It was under grants from the National Research Council that Dr. Kinsey collected material for his famous Kinsey Report. In that report, 317 children were reported to have been subjected to sexual molestation, and their responses recorded in a graph table. Nowhere is there evidence that parental consent was given. In fact, no one, not even parents, could give consent for such acts, but that didn't stop the Kinsey "scientists."

Further documentation of this shameful episode of scientific abuse can be found in the Family Research Council's new documentary, "The Children of Table 34," which I am donating and submitting for the record. It can also be found in "Kinsey Sex and Fraud, The Indoctrination of a People," by Dr. Judith Reisman, Edward Eichel, with Drs. J. Gordon Muir and John Court as editors.

Now, I am not suggesting that the mere taking of a survey is equivalent to the kind of abuse that Kinsey recorded, just that there is a temptation to gather information because it can be done without asking whether it should be done.

Surveys that ask questions about suicide or drug use can plant the idea of either activity as an option, when a teen may never have entertained this option. Through sheer repetition of reference, harmful activities can lose their power to inspire natural resistance. After all, if a teen hears about this stuff, a teen could conclude: If we are talking about it so much, everybody must be doing it, what's wrong with me?

Sex surveys in and of themselves are objectionable when directed toward children, and they are notoriously unreliable. They are slanted toward the unconventional. People who indulge in unconventional sexuality or precocious sexuality are far more interested in talking about it.

Here is the dilemma for little Susie. She responds to a question that asks if she is a virgin. If she answers yes, then she is supposed to skip through several detailed questions about sexual activities, such as how many partners she has had. After an exercise

like that, she may feel like a sexual underachiever for having kept herself chaste. Teens are very peer conscious and can feel left out and stigmatized for having to exempt themselves from a battery of questions. Likewise, if the onus is on the parent to opt a child out of intrusive experiences, the possibility for stigma is greater than if all parents have to opt their children in with written consent. Those who administer surveys are more interested in high compliance than parental input, so they tend to be opposed to such safeguards. But parental rights have to come first.

The Family Research Council supports efforts like H.R. 1271 to safeguard the rights of parents to direct their children's education and welfare, and that includes how, where, and when children are included in research. Parents are assigned that task by no less an authority than God Himself. It would be the epitome of hubris to tamper with that bond because some educational experts feel they are smarter than everybody else.

Thank you.

[The prepared statement of Mr. Knight follows:]

PREPARED STATEMENT OF ROBERT H. KNIGHT

Thank you for inviting me to speak on behalf of the Family Research Council, and, by extension, on behalf of many parents all over the United States.

In the 1986 White House Working Group on the Family, the Final Report included these words:

"Parental nurturing and education of the young is our most important national investment. It is the fundamental task of humanity."

Notwithstanding a few cataclysmic events, such as the collapse of the Soviet empire, nothing has happened since then to alter the truth of this observation, penned by Gary Bauer, who is now president of Family Research Council. Indeed, it could have been said at any time and in any place.

We often hear from child rights advocates that, "It takes a village to raise a child," but parents are indispensable. Not even a whole village can replicate them. As the people most responsible for and most equipped to discern the needs of their children, parents must be accorded deference in all matters related to education. Children in public and private schools are taught by dedicated professionals, but only because the parents consent to have these professionals participate in their children's education.

No one but a parent can understand how parents feel about their own children. And I am talking about adoptive parents as well as biological ones.

Mother Teresa described such devotion through a first-hand observation at her clinic in India:

"I never forget, I gave a child to a Hindu family, and after a few months, I heard that the child became very, very sick. And I sent for the family, and I told them, give me back that child. I'll take care of the sick child, and I'll give you another healthy child. And the father looked at me and said, 'Mother, take my life rather than take the child.'"

Like this Indian father, most parents would lay down their lives for their children. And they are acutely aware of their responsibility. So decisions about what kind of information is conveyed to children or extracted from them are the parents' natural prerogative.

Any research methods that place a barrier between children and their parents should be outlawed. Increasingly, parents have found themselves fighting for their most fundamental rights against some hostile educators and government officials who honestly believe that they know what is best for children, not parents. Such officials work overtime to acquaint children with revisionist history, graphic sexual materials and relativistic notions of morality—all in the name of education.

Often, parents are unaware of what the children are receiving. The concept of informed consent is faulty because there are too many ways for it to fail. A teacher may send a child home with an announcement about an upcoming survey, but unless the parent signs a permission form, there is no way to determine if the message got through. To critics who argue that written requirements are cumbersome and expensive, we answer that a loss of parental freedom to determine a child's edu-

cation is a far higher cost—one that is unacceptable. Besides, there are other ways that information can be obtained on dangerous behaviors. The number of cases of out-of-wedlock pregnancies, sexually transmitted diseases, suicides, drug overdoses and the like is readily available. The drive to target all teens because of the actions of the unfortunate few is a manifestation of the educational dogma that information in and of itself, with no moral reference, can make a difference. But two decades of research have shown that giving youngsters more information about sex, for instance, has not resulted in any behavioral change, except perhaps earlier experimentation.

With the advent of Goals 2000, and its emphasis on national standards and accountability, the role of testing is becoming paramount. Outcome-based-education, as implemented by Goals 2000, moves schools away from the strictly academic and toward the production of certain "attitudes." Consequently, the line is becoming blurred between what is educational and what is therapeutic.

Parents are concerned over surveys for two reasons:

(1) Some questionnaires may reveal information that is nobody's business but that of the family; and (2) some questionnaires convey information to which parents would rather not expose their children.

The issue of parental consent for research has been driven primarily by a spate of recent sex, suicide and drug surveys among young teens, some of which have been politically motivated and manipulated. A few years ago, a national youth survey on sexuality contained questions that were so graphic as to be, in many parents' estimation, pornographic.

Concern over research on hapless children has also been driven by revelations of abuses by federally-funded researchers going as far back as the sex studies of Dr. Alfred C. Kinsey in the 1940's. It was under grants from the congressionally chartered National Research Council that Dr. Kinsey collected materials for what became known as the Kinsey Report, the largest sex survey ever at that time. Under the rubric of science, some 317 children were subjected to sexual molestation, and their responses recorded in graph tables. Nowhere is there evidence that parental consent was given for what were clearly criminal acts. In fact, no one, not even parents, could give consent for such acts, but that did not stop the Kinsey "scientists."

Further documentation of this shameful episode of scientific abuse can be found in the Family Research Council documentary video *The Children of Table 34,* which I am submitting for the record, and in *Kinsey Sex and Fraud, The Indoctrination of a People,* by Dr. Judith A. Reisman, Edward W. Eichel, with Drs. J. Gordon Muir and John Court as editors (Huntington House: 1990).

Now, we are not suggesting that the mere taking of a survey is equivalent to the kind of abuse that Kinsey recorded. Just that there is a temptation to gather information because it *can* be done without asking whether it *should* be done.

Sometimes, the impact on the survey taker seems almost calculated to increase curiosity into deviant behavior. Surveys that ask questions about suicide or drug useage, for example, can plant the idea of either activity as an option, when a teen may never have entertained the thought before. Through sheer repetition of reference, harmful activities can lose their power to inspire natural resistance. After all, a teen may reasonably conclude: "If we are talking about all this stuff so much, doesn't that mean that everybody is doing it?"

Sex surveys are particularly objectionable. Little Susie responds to a question that asks if she is a virgin. If she answers yes, then she is supposed to skip through several detailed questions about sexual activities, such as how many partners she has had. After an exercise like that, she may feel like a sexual underachiever for having kept chaste. Teens are very peer conscious, and can feel left out and stigmatized for having to exempt themselves from a battery of questions. Likewise, if the onus is on the parent to opt a child out of such intrusive experiences, the possibility for stigma is greater than if all parents have to opt their children in. Those who administer surveys are more interested in high compliance than parental input, so they tend to be opposed to such safeguards. But in the scheme of things, parents rights must come first.

Family Research Council supports efforts to safeguard the rights of parents to direct their children's education and welfare, and that includes how, where, and when children are included in research. Parents are assigned that task by no less an authority than God Himself. It would be the epitome of hubris to tamper with that bond because some educational experts feel they are smarter than everybody else.

Senator STEVENS. Thank you, Mr. Knight.

Next, Dr. Hilton.

TESTIMONY OF MATTHEW HILTON, J.D., PH.D., SPRINGVILLE, UTAH

Dr. HILTON. Thank you, Chairman Stevens. I would like to just spend a few minutes today and give you some perspective as a litigating civil rights attorney and also one who holds a Ph.D. in curriculum and instructional science.

These past 2 years I have had the opportunity of litigating a case in Utah for a young family. They had children in second and third grade enrolled in a Chapter I program, totally federally funded. Without disclosure, to their parents, one of the psychological tests that Senator Grassley included in the Congressional Record as an offensive test was given to these children. The school asked 7- and 8-year-olds to engage in a self-labeling process to measure their self-esteem. Some of the questions the parents were objecting to when they found out later about the test included: I cause trouble to my family, yes or no; I think bad thoughts, yes or no; I behave badly at home; I pick on my brothers and sisters; my parents expect too much of me; my family is disappointed in me.

The parents approached the district and requested the children not be tested again. Contrary to the representation that testing wouldn't be done until the end of the year, (ironically the very day that the Grassley amendment was being debated in the Senate), these children were retested again. To make matters worse, the older child objected to the district and said, My mother said I can't take this test. And the child was promptly reassured, according to the child's account and in the court pleadings that have been uncontested that, oh, it's okay, honey, we've already talked to your mother, go ahead and take the test.

After this occurred, litigation was filed trying to enforce their parental rights. After a year-and-a-half in court (and effective as of yesterday when I received in the mail an order from the court denying a motion to reconsider), a Federal judge ruled that these parents have no enforceable rights under the existing Federal laws on funding because Congress failed to provide a private right of action; and, second, that there is no constitutional violation because this judge felt there was no substantial interference whatsoever with any liberty interest of the parent.

For these reasons, I am here today to strongly support the adoption of H.R. 1271, as suggested with amendments by Senator Grassley, and suggest that a couple of other areas be clarified. I have submitted a rather detailed written report for the record, Mr. Chairman, for your staff, but let me review just one or two of those real briefly.

On page 3, there is an exemption on lines 3 through 5 that says any inquiry made pursuant to a good-faith concern for the health, safety, or welfare of an individual minor. That is written so broadly you could argue that this prior testing on self-esteem could have come under that category. In fact, that was one of the arguments that was used, that the school district was just trying to help and be helpful.

I have specifically recommended that you pattern this after a Utah law adopted in the very year our run-in with this district occurred. Our State unanimously in 1995 reaffirmed this law that bans all such testing, regardless of source of funding, regardless of

whether it is school activity or curricula. Anywhere, any time in our school, you can't do any of this kind of testing. In fact, some of the clarified language you have comes out of the Utah statute.

In our statute, we say you do have an exemption if it is reasonably believed to be an emergency or authorized by State child abuse and neglect laws. All States have reporting for child abuse and neglect laws. We don't intend to undermine those. But as written, your exemption is far too broad.

Second, lines 17 through 25 on page 3, you are allowing all the different departments to set up their own consent forms. We have recommended to the contrary in my testimony specific language that we have used in Utah. We have amended the Utah law and clarified it again this year. We hope that it would be sufficient to make sure there is adequate consent and notice given.

The school district in the litigation I referred to argued in their briefs on the motion to reconsider that they had given consent because they did have one line that said a pre- and post-test will be given. Nowhere did they disclose it would be a self-esteem psychological examination, self-labeling of the child regarding his parents and those relationships. We need to have greater clarification given on that.

Finally, I am very concerned about a right to private action. We had extensive discussion in the House. They felt the language they put in on page 4, lines 6 through 7, would be adequate. What is there seems to me to still be ambiguous, having litigated the matter extensively and written this other State legislation. I would recommend, as noted in my letter, that lines 6 through 7 on page 4 be rewritten to say "regardless of any administrative action, any private person aggrieved because of a violation of this act may bring an action for relief under 42 U.S.C. Section 1983 in Federal or State court."

Lest there be any question, we are not waiting for pending administrative rulings; we are not waiting for local decisions. If we have an infringement, we need to empower parents to enforce it. If we are trying to protect parental privacy and autonomy, we surely have to make sure there is no question those same parents have the right to defend and enforce their rights, especially if we have a sitting Federal judge who says there is no constitutional violation whatsoever and that this is just a de minimis liberty interest.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Hilton follows:]

PREPARED STATEMENT OF MATTHEW HILTON, J.D., PH.D

Thank you for the opportunity to suggest possible amendments to H.R. 1271 presently before this Committee. My comments are derived, in part, from litigating in Federal court claims seeking private enforcement of 20 U.S.C. § 1232h ("PPRA"), serving as primary draftsman of Utah legislation entitled the Educational Rights and Privacy Act (§§ 53A–13–301, 302 U.C.A), and teaching as an adjunct professor in the College of Education at Brigham Young University. I have included with my letter copies of the 1995 version of the Utah privacy legislation as well as the order of a Federal judge dismissing all statutory and constitutional claims associated with parental prerogatives over the psychological testing of their children in the public schools when involved in programs that are funded solely with Federal funds. I previously testified before the House Committee from whence H.R. 1271 originated. I am again appearing today as a private citizen.

I strongly support what I understand is a serious effort of this Committee to protect family privacy and autonomy. "[T]he liberty interest in family privacy has its source, and its contours are ordinarily to be sought, not in State law, but in intrinsic human rights, as they have been understood in 'this Nation's history and tradition.'" *Smith v. Organization of Foster Families,* 431 U.S. 816, 842 (1977) (plurality opinion) (citations omitted). "The history and culture of Western civilization reflect a strong tradition of parental concern for the nurture and upbringing of their children. The primary role of parents in the upbringing of their children is now established beyond debate as an enduring American tradition." *Wisconsin v. Yoder,* 406 U.S. 205, 232 (1972). These beliefs, however, have not received universal application.

A Federal judge recently determined (without articulated analysis) that the following fact pattern did not state a claim upon which Federal statutory or constitutional relief could be granted:

> In 1993, parents new to an area enrolled their two children in public school. The children were placed in a federally-funded program called Chapter 1 which was designed to assist them with basic reading and other academic skills. No disclosure was made or consent obtained for the administering of certain self-esteem tests to the children. During the course of the program, and following a traditional practice in the district, a self-esteem test that had been used elsewhere as a tool of psychiatric evaluation was given to all of the students in the Chapter I program.
>
> When the children's mother attended parent-teacher conference that fall, the mother found that the children had been given this self-esteem test without her or her husband's knowledge or consent. Among other things, the mother of these children objected that their second and third grade students were required to respond to the following questions and self-label themselves with a yes or no answer:
>
> I cause trouble to my family Y—— N——
> I behave badly at home Y—— N——
> I pick on my brothers and sisters Y—— N——
>
> The children were also asked to label their family as follows:
>
> My parents expect too much of me Y—— N——
> My family is disappointed in me Y—— N——
> I am picked on at home Y—— N——
>
> Upon learning that this testing was given, the mother immediately contacted her children's teachers, counselors and the district office and explained that her children were not to be tested in this manner. She also indicated that she believed such testing—without her written consent—violated certain Federal law.
>
> Therefore, the school district chose to re-test the same Chapter I students. The older of the two children reported to his mother that he had objected to taking the test but that the test was readministered with the assurances from district staff that they had spoken with his mother. After the second testing, the mother learned of existing district policy which provided that "the home, community, and the school are jointly responsible for the physical, social, emotional and moral development of the youth."[1]

The plaintiffs in the litigation have requested that the recent order of the Federal judge dismissing the case be amended to reinstate their constitutional claims dealing with infringement on parental and familial privacy, autonomy and due process. It is argued that the constitutional claims arise because the parents either had not been notified of the testing, were notified erroneously of the date when the testing was to occur, or were not notified that inclusion in a Chapter I reading program required submission to psychological "self-labeling," "self-esteem" testing. There is no request to give parents a unilateral right to dictate that public schools revise their curriculum; rather, the Rule 59 F.R.C.P. motion seeks to ensure clarify a fundamental right in parents to receive adequate notice of invasive, psychological testing so that they may choose to remove their children from the experience. Issues raised by the local school district in response to the request for constitutional analysis indicate that significant constitutional issues have been forgotten when govern-

[1] See Policy 1.1 of Alpine School District.

ment is using Federal funds to elicit disclosure of information from children without disclosure of the action to parents.

As a general rule, parents and teachers may not impose their personal beliefs and world views on the curriculum of an unwilling school district.[2] Parents, may, however, seek to have their children removed from certain practices on free-exercise or speech grounds.[3] The challenge facing the parents in the Utah litigation—and any other parent whose children are subject to testing by any entity using Federal funds—is that if disclosure is not made beforehand, the right to parental autonomy and family privacy will necessarily not be exercised for lack of knowledge. The testing used to measure "self-esteem" was (by expert affidavit) of a"non-academic" nature, a non-traditional activity in the schools. When schools or other government entities engage in this type of activity, it can not be presumed that parents will either know or consent to the same.[4] Furthermore, the leading cases rejecting objections to curricula have generally limited their legal analysis to matters involving the exercise of conscience by a parent or teacher when full knowledge of the requirements and situations of students was had by all parties. To the degree that the testimony provided before the administrative rules of the PPRA were first promulgated remains an accurate reflection of current conduct in public schools,[5] there remains much that the Senate may do to encourage protection of family privacy and parental autonomy.

As this Committee considers options to clarify what familial privacy and parental autonomy it will protect, the members can be assured that there will be conflicting views regarding the political rationale and propriety of taking such action. For example, the political assumptions that accompany such clarification may be fundamentally different. If one is of the political persuasion that all persons are "endowed by their Creator with certain unalienable rights,"[6] and that the parent-child relationship is one of those rights, this clarifying legislation will not create more rights but simply serve to clarify to what degree the existing Federal Government will choose to protect those inherent rights. On the other hand, if one holds a more positivist view and believes that government itself is the creator and ultimate protector of rights, then clarifying legislation can eliminate some of the confusion that has existed regarding the prerogatives of parents over their children's involvement in non-academic, non-traditional school curricula or other invasive governmental intrusion into lives of parents, children, and families.

Just as foundational political assumptions may differ, in similar fashion, individual parental response may reject or welcome governmental involvement in the raising of one's children. When government is allowed

> to encroach upon the patterns of molding a child's behavior and personal, family or religious beliefs[,] [p]arental discipline, authority and respect diminish as the great Sovereign state forces its way into the homes as a foster parent. Some parents may be happy to be relieved of the obligation and responsibility. Others may feel that the constant eroding of their usefulness as parents portends great danger, and youth will look to the State rather than the parent, for guidance.[7]

Allowing and protecting family autonomy and privacy will enable those who choose to shoulder the heavy responsibilities and duties of caring for children (without necessarily agreeing with official government positions) to contribute to the rich, cultural diversity that characterizes America today. Indeed, in the words of then Justice Dallin Oaks, speaking for the Utah Supreme Court,

> family autonomy helps to assure the diversity characteristic of a free society. There is no surer way to preserve pluralism than to allow parents max-

---

[2] Leading cases in this area include *Mozert v. Hawkins County Board of Education,* 827 F. 1058 (6th Cir. 1987) *cert. denied* 484 U.S. 1066 (1988) and *Roberts v. Madigan,* 921 F.2d 1047 (10th Cir. 1990) *cert. denied* 112 S.Ct. 3025 (1992).

[3] *See West Virginia State Board of Education v. Barnette,* 319 U.S. 624 (1943).

[4] For other types of objections parents have raised to non-traditional, non-academic activities, *see Alfonso v. Hernandez,* 606 N.Y.S.2d 259 (A.D.2 Dept. 1993) (school program for distribution of condoms restricted as against students of parents' objecting because it was a health rather than academic activity); *Merriken v. Cressman,* 364 F.Supp. 913 (E.D.Pa. 1973) (student participation in a self-labeling program to aid in the stopping of drug usage could lead to self-fulfilling prophecies and interfere with parent-child relationships.)

[5] One of the earliest, comprehensive documentaries of these activities was reported in Phyllis Schlafly, ed., *Child Abuse in the Classroom* (1984) which published testimony from parents given at Congressional hearings around the Nation about objectionable, undisclosed, educational practices.

[6] Declaration of Independence.

[7] *Valent v. New Jersey State Board of Education,* 274 A.2d 832, 838 (N.J. Super.Ch.Div. 1971).

imum latitude in rearing their own children. Much of the rich variety of American culture has been transmitted from generation to generation by determined parents who were acting against the best interest of their children, as defined by official dogma.[8]

Regardless of one's world view or personal conduct regarding one's children, careful legislative clarification[9] could help in resolving the inevitable conflicts that arise when government seeks to actively become involved in families and parental decision-making.[10]

Desiring to further protect interests of family autonomy and privacy, and expressing grave concern regarding the result of the Utah litigation outlined above, I would recommend that H.R. 1271, as presently written, be revised to address issues raised by the following three questions:

(1) Are there convincing reasons why the legislation does not have basic factual or policy findings to justify the family privacy protections that are obviously desired by this legislation?

It is appropriate for the Committee to consider adopting as a preamble to the legislation certain factual or policy statements. You may wish to consider the following as a newly created Section 2 to the current legislation:

Section 2: Legislative Intent and Findings: It is the intent of Congress to ensure that the rights of parents and children to family privacy and autonomy are protected. Protecting these rights is a compelling interest of government because:

(a) the rights that are present in a parent-child relationship in a family unit are presumed to part of that process by which all people are endowed with certain inherent and inalienable rights by their Divine Creator, which relationship and rights have a natural or prior existence to those that exist with government;

(b) the family unit is where parents have the right and responsibility to transmit their own rich cultural traditions regarding deeply held values, religious beliefs and practices, other moral views, political views and other aspects of heritage that is part of the family life in the home;

(c) the family unit is the primary location where parents and children develop integrity, diligence, kindness and courtesy and other traits of character necessary for democratic values and institutions to flourish;

(d) the family unit is the foundation of a stable society; and

(e) intrusion by government into the privacy and autonomy of the family unit tends to undermine the ability of members of the family to exercise rights and responsibilities which provide these critical benefits to society.

Thus, at all times, family privacy and autonomy is to be given greater preference than administrative convenience and protected as outlined hereafter.

Rather than requiring parents to rely on (and seek to judicially expand) language in Supreme Court opinions that have upheld substantive due process rights of parents in certain situations, by articulating and clarifying Congressional intent now,

---

[8] *In re J.P.*, 648 P.2d 1364, 1376 (Utah 1982).

[9] An interesting question that the Committee could address focuses on the interfacing of this legislation with rights afforded under the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. § 2000bb. At present, RFRA requires a "substantial burden" to be imposed on one's free exercise rights before a right to object to a general law exists. Since H.R. 1271 seeks to eliminate burdens on parental autonomy and family privacy by requiring written, affirmative consent before certain information can be disclosed at all, it could be understood to be a Congressional decision to be that parental autonomy and family privacy (as it relates to disclosure of certain types of information by minors) should be afforded greater protection than allowed under RFRA. Such a position could be justified because (as evidenced by the Utah litigation) without full and complete disclosure to parents of governmental efforts to obtain information from minor children, the parent will have no knowledge of the interference and will not be aware of any possible need to exercise any right, whether it be free-exercise of religion, family privacy, or parental autonomy.

[10] Governmental interests could well be protected by adopting comprehensive legislation that protects family privacy. For example, if H.R. 1271 is expanded to include public education, careful and sensitive articulation of Congressional assumptions and statutory guidelines regarding family privacy and parental autonomy can (1) encourage students and their families to internalize values of their own choosing, (2) encourage greater confidence in our parents of the ultimate appropriateness of the school curricula and school activities that are provided for their children, (3) eliminate confusion which invites litigation, (4) facilitate professional interaction with and support of the parents in our communities, (5) create greater confidence in our teachers of the appropriateness of their curricula selections, and (6) facilitate professional training of employees.

Congress can take affirmative steps to ensure that parents, children, and families will receive more protection from future regulations and judicial decisions because this legislation will be crafted by Congress to ensure that the government's compelling interest in stable and lasting families, family privacy, and parental autonomy will be honored by the Federal Government and those receiving Federal funding.

(2) Are there convincing reasons why the provisions of his act and those addressed in the Protection of Pupil Rights Amendments of 1994 can not be jointly addressed?

In 1994 the United States Congress revised statutory law (commonly known as the Protection of Pupil Rights Amendments of 1994. The origin of these protections were in the Senate. A needed revision in the law was provided. Even though H.R. 1271 has exempted the effect of its requirements on public education, *see* Section 2, page 2, lines 3–4; Section 6, page 4, lines 12–15), during the House Committee hearings it was observed that the overwhelming majority of all testing that occurs with Federal funds occurs in the public schools. Since it appears that H.R. 1271 provides, among other things, more protections for parental privacy by (1) expanding the various categories of prohibited information and (2) provides a private right of action, it would seem that if the intent of the Senate is to protect family autonomy and privacy rights, the provisions of PPRA should be similarly be expanded to include similar protections. to do this, at a minimum, the noted exceptions would have to be removed from H.R. 1271.

Broadening the scope of protection afforded by H.R. 1271 is not in conflict with the recent Supreme court ruling allowing testing of high school athletes for drug usage.[11] This so for at least three reasons. First, there was no question in the court's opinion that adequate disclosure had been made of the requirement that all athletes submit to the requirement of random testing. (A failure to properly disclose actual or intended conduct and allow parent directed withdrawal are among the issues addressed by this legislation.) Second, unlike a right to participate in extracurricular athletics, the right to family privacy and parental autonomy has a long history of recognition of in both our culture and constitutional law. Third, even if applicable, "a wise public policy . . . may require that higher standards be adopted than those minimally tolerable under the Constitution."[12] In all events, "[i]n our system, state-operated schools may not be enclaves of totalitarianism. School officials do not possess absolute authority over their students."[13]

(3) Are there convincing reasons why much of the language in the proposed amendment is written so broadly, ambiguous in parts, or that terms of consent are not defined?

Actions of the United States Supreme Court have recognized that administrative agencies have expansive power in implementing policy decisions arising from ambiguous legislation. While not consistently applied by the court,[14] beginning in 1984 the Court created a two-step process by which it determined it would give great deference to an administrative interpretation of an ambiguous statute.

> When a court reviews an agency's construction of the statute it administers, it is confronted with two questions. First, always, is the question of whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress, If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question is whether the agency's answer is based on a permissible construction of the statute.[15]

---

[11] *See Veronia School District 47J v. Acton,* 115 S.Ct. 2386 (1995).

[12] *Lassiter v. Department of Social Services,* 452 U.S. 18, 33 (1981).

[13] *Tinker v. Des Moines Independent Community School District,* 383 U.S. 503, 511 (1969).

[14] *See* Kenneth Culp Davis and Richard J. Pierce, *Administrative Law Treatise,* Vol. I, § 3.6 at 123–131 (1994); Thomas W. Merrill, "Judicial Deference to Executive Precedent," 101 Yale Law Journal 969 (1992).

[15] *Chevron v. Natural Resources Defense Council,* 467 U.S. 837, 842–843 (1984). The administration of some statutes—such as the 1994 amendments to PPRA—seems to go a step further. Indeed, the Department of Education intends to allow those involved in education to design their own consent standards (Federal Register, Vol. 60 No. 166, at 44697, August 28, 1995) and determine when, in their judgment, a student is "required" to disclose the information. *Id.* If PPRA is amended to include the standards suggested in this letter, the potential confusion arising from this administrative determination can be eliminated to a significant degree.

Based my experience in developing and litigating privacy laws in Utah, it would seem that various provisions of the language in the present version of H.R. 1271 need to be clarified so as to avoid inadvertent judicial or administrative misconstruction of the intended effort of Congress to protect family privacy and autonomy:

1. The provisions of page 3 lines 3–5 exempt "any inquiry made pursuant to a good faith concern for the health, safety, or welfare of an individual minor." It could be argued that the offensive psychological tests referred to in the factual occurrence litigated in Utah could be classified as being in this category because the school was trying to measure (and define) a student's self-esteem to promote the well-being of the student. To avoid such confusion, I would suggest that language be substituted that more closely tracks the provisions of §53 A–13–302 (4)(a) U.C.A. (1995) which suggests a more narrow limitation in that the requirements for written consent would not apply when responding *"to a situation that is reasonably believed to be an emergency or authorized by State child abuse or neglect reporting laws."*

2. The provisions of page 3, lines 16–25 allow any Federal department or agency to develop their own rules for notification. I strongly suggest that the Federal standard be a unified standard that applies to all agencies or recipients of Federal funds and be more explicit in its requirements regarding consent. I would suggest language be substituted that more closely tracks the provisions of §§53A–13–302(3), 4(c) and (d) U.C.A. (1995) as follows:

Written parental consent is valid only if a parent, legal guardian, or person charged with custodial duties has been first given written notice and a reasonable opportunity to obtain written information concerning:

(a) records or information, including information about relationships, that may be examined or requested;
(b) the means by which the records or information shall be examined or reviewed;
(c) the means by which the information is to be obtained;
(d) the purposes for which the records or information are needed;
(e) the entities or persons, regardless of affiliation, who will have access to the personally identifiable information; and
(f) a method by which a parent of a student can grant permission to access or examine the personally identifiable information.

Written consent may be withdrawn by a parent at any time and is not valid after the completion of the specific task for which it was given. A general consent used to approve admission into any program or activity does not constitute written consent under this section.

3. Following the pattern of §§53A–13–302(1)(a), (1)(c), and (1)(e) U.C.A. (1995), I would recommend that the prohibited categories be expanded under Section 2(a) line 13, to read: *"(1) "Parental or family member political affiliations, philosophies, or beliefs;"* line 15 be changed to read *"(3) Sexual behavior, orientation, or attitudes;"* and lines 18–19 be changed to read *"(5) Appraisals of other individuals with whom the minor or family member has close family relationships."*

4. The term "academic performance tests" is undefined on page 3, line 11–15. Is the term intended to include the "self-esteem" tests referred to in the Utah litigation? Because this term could be considered to be ambiguous, it should be clarified, (or if merged with PPRA), eliminated.

ATTACHMENT 1

ORDER DISMISSING COMPLAINT WITH PREJUDICE

CIVIL NO. 94–C–181G

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH
CENTRAL DIVISION

D.P. and A.P. for themselves individually, and for their children B.P. and N.P.,

Plaintiffs,
vs.

LUANA SEARLE, VICTORIA ANDERSON, REBECCA RIGBY, in their official and personal capacities and ALPINE SCHOOL DISTRICT, a government entity,

Defendants.

The Motion of the Defendants in the above entitled matter to dismiss all claims with prejudice came on before the Court on 21 February 1995 at 10:30 a.m. The Plaintiffs were present and represented by their counsel of record Matthew Hilton. The Defendants were represented by their counsel of record Blake T. Ostler.

The Court has considered the extensive briefing of all matters in this case. The parties stipulated that the Motion to Dismiss extends to both the most recently filed pleadings and the Motion to File a Second Amended Complaint in the matter.

Having been fully advised and for good cause shown, the Court makes the following Findings of Law:

1. The Plaintiff's First Claim, brought under 20 U.S.C. § 1232h, the Protection of Pupil Rights Amendment, must be dismissed with prejudice for failure to state a claim for the following reasons:

(a) There is no private right of action by the Plaintiffs to assert claims in this Federal Court under 1232h because the statute does not provide such a right and the comprehensive enforcement scheme, under 20 U.S.C. § 3474 evinces an intention by Congress to preclude a private right of action, following controlling law in the case of *L'ggrke v. Benkula,* 966 F.2d 1346, 1347 (10th Cir. 1992);

(b) The Piers-Harris Children Concept Scale, administered in connection with a reading and self-concept program, does not constitute impermissible psychological or psychiatric testing under 20 U.S.C. § 1232h because its primary purpose was not to reveal the types of information enumerated in that statute.

(c) There is a presumption that no private right of action is intended where there is a comprehensive enforcement scheme and Plaintiffs have not overcome that presumption.

2. The Plaintiff's claims brought under 42 U.S.C. §§ 1983 and 1988 must be dismissed with prejudice because the comprehensive enforcement scheme which provides for the Secretary of Education to enforce the provisions of § 1232 would be frustrated by allowing a private right of action and for the reasons stated above;

3. The Plaintiffs' claim for violation of Due Process must be dismissed with prejudice for the reasons stated above and in addition because the Plaintiffs have failed to identify any substantial liberty or property interest that was violated by Defendants and, in addition, assuming the applicability of § 1232h, the Defendants complied with all requirements of the statute;

4. The Plaintiff's claims for violation of a constitutional right to familial association must be dismissed with prejudice for failure to state a claim for the following reasons:

(a) The Plaintiffs have failed to allege the requisite intent to state a claim under *Trujillo v. Board of County Comm'rs,* 768 F.2d 1186, 1183 (10th Cir. 1985);

(b) The Plaintiffs have not and cannot allege well-plead facts that arise to the level of an interference with familial association under the Tenth Circuit's decision in *Griffin v. Strong,* 983 F.2d 1544, 1549 (10th Cir. 1993);

(c) The Plaintiffs have not and cannot allege well-plead facts that show that the Defendants acted knowing that their conduct would adversely affect the familial relationship as required by *Griffin v. Strong;*

5. The Plaintiffs have not and cannot allege facts showing any implication or violation of the constitutional rights to control the upbringing of children how they wish, to refuse unwanted medical treatment or any violation of the Ninth or Fourteenth Amendments as alleged in the proposed Second Amended Complaint;

6. The individual Defendants are entitled to qualified immunity;

7. All of Plaintiff's remaining motions are rendered moot by this judgment.

8. Allowing the Plaintiffs to file their Second Amended Complaint would be futile for the reasons set forth above.

THEREFORE, it is hereby ORDERED, ADJUDGED AND DECREED that the claims of the Plaintiff asserted in the Amended Complaint and also in the Second Amended Complaint are hereby DISMISSED WITH PREJUDICE.

DATED this 8th day of September, 1995.

BY THE COURT:
J. Thomas Greene
U.S. District Court Judge

Approved as to Form:

Matthew Hilton
HILTON & STEED, P.C.
Attorneys for Plaintiffs

ATTACHMENT 2

ENROLLED COPY H.B. 57

EDUCATIONAL RIGHTS AND PRIVACY ACT AMENDMENTS

1995 GENERAL SESSION—STATE OF UTAH

SPONSOR: SHIRLEY V. JENSEN

AN ACT RELATING TO PUBLIC EDUCATION; PROVIDING THAT THE PUBLIC EDUCATION SYSTEM SHALL PROTECT THE PRIVACY OF STUDENTS, THEIR PARENTS, AND THEIR FAMILIES; PROVIDING FOR A WAIVER; PROVIDING FOR WITHDRAWAL OF AUTHORIZATION TO DISCLOSE; PROVIDING AN EXCEPTION; AND MAKING TECHNICAL CHANGES.

This act affects sections of Utah Code Annotated 1953 as follows: [deletions in **bold**, additions in *ital*]

AMENDS:
53A–13–301, as enacted by Chapter 267, Laws of Utah 1994
53A–13–302, as enacted by Chapter 267, Laws of Utah 1994

Be it enacted by the Legislature of the State of Utah:

Section 1. Section 53A–13–301 is amended to read:

53A–13–301. Application of State and Federal law to the administration and operation of public schools.

(1) Employees and agents of the state's public education system shall **[comply]** *protect the privacy of students, their parents, and their families, and support parental involvement in the education of their children through compliance* with the protections provided for family and student privacy under *Section 53A–13–302 and* the *Federal* Family Educational Rights and Privacy Act**[, as enacted by the United States Congress,]** *and related provisions under 20 U.S.C. 1232 (g) and (h),* in the administration and operation of all public school programs, regardless of the source of funding.

(2) Each public school district shall enact policies governing the protection of family and student privacy as required by this section.

Section 2. Section 53A–13–302 is amended to read:

53A–13–302. Activities prohibited without prior written consent—Validity of consent—Qualifications.

Policies adopted by a school district under Section 53A–13–301 shall include prohibitions on:

(1) the administration *to a student* of any psychological or psychiatric examination, test, or treatment, *or any survey, analysis, or evaluation* without the prior written consent of the student's parent or legal guardian, in which the purpose of *evident intended* effect is to *cause the student to* reveal information, *whether the information is personally identifiable or not* concerning the student's or any family member's:

(a) political affiliations or, *except as provided under Section 53A–13–101.1 or rules of the State Board of Education, political* philosophies;
(b) mental or psychological problems;
(c) sexual behavior, orientation, or attitudes;
(d) illegal, anti-social, self-incriminating, or demeaning behavior;
(e) critical appraisals of individuals with whom the student or family member has close family relationships;
(f) religious affiliations or beliefs;
(g) legally recognized privileged and analogous relationships, such as those with lawyers, medical personnel, or ministers; and
(h) income, except as required by law.

(2) The prohibitions **[regarding the inquiry or disclosing of information]** under Subsection (1) shall also apply **[to]** *within* the curriculum **[or]** *and* other

school activities unless prior written consent of the student's parent or legal guardian has been obtained.

(3) Written parental consent is valid only if a parent or legal guardian has been first given written notice and a reasonable opportunity to obtain written information concerning:

(a) records or information, including information about relationships, that may be examined or requested;
(b) the means by which the records or information shall be examined or reviewed;
(c) the means by which the information is to be obtained;
(d) the purposes for which the records or information are needed;
(e) the entities or persons, regardless of affiliation, who will have access to the personally identifiable information; and
(f) a method by which a parent of a student can grant permission to access or examine the personally identifiable information.

(4)(a) Except in **[the case of exigent circumstances]** *response to a situation which a school employee reasonably believes to be an emergency, or as authorized under Title 62A, Chapter 4a, Part 4, Child Abuse or Neglect Reporting Act, or by order of a court,* disclosure to a parent or legal guardian must be given at least two weeks**[, but not more than five months]** before information protected under this section is sought.

(b) Following disclosure, a parent or guardian may waive the two week minimum notification period.

(c) Parental authorization shall be valid until the commencement of the subsequent school year or until one of the following occurs:

(i) the child completes or withdraws from the course, activity, or program for which it was granted; or
(ii) a written withdrawal of authorization is submitted to the school principal by the authorizing parent or guardian.

[b] *(d)* A general consent**[, including a general consent]** used to approve admission to *school* or involvement in **[a]** special education **[or]**, remedial **[program or regular]** *education, or a* school activity*[,]* does not constitute written consent under this section.

(5) This section does not limit the ability of a student under Section 53A–13–101.3 to spontaneously express sentiments or opinions otherwise protected against disclosure under this section.

Senator STEVENS. Thank you. Did you raise the Tenth Amendment in your case that you just mentioned?

Dr. HILTON. No, I did not. What my issue on the States was that a State may impose restrictions regardless of funding. Our State said, well, we are going to go a step further, and it is going to apply to any program. I think States do have the right to broaden that. But there was no Tenth Amendment issue per se. There were rights of privacy, rights of a parent to refuse medical care for their children, a right to due process, right to parental autonomy. All of those were constitutional issues that we claimed were violated.

Senator STEVENS. I know Mr. Mathias made reference to the Tenth Amendment. We have the Tenth Amendment under investigation right now in terms of violations of the Tenth Amendment. It does seem to me that Federal funds cannot mandate that a State give up its Tenth Amendment rights or those within the State give up their Tenth Amendment merely because there are Federal funds involved in financing of programs that were never really covered by a constitutional delegation as far as the States or the people are concerned.

Dr. HILTON. That is absolutely correct, Mr. Chairman, but part of the dilemma in this case is that not only were they using the Federal funds, but in our opinion, they were using them contrary to the very Federal mandate that they had Federal constitutional

law. We couldn't really claim a Tenth Amendment violation there. But you are absolutely right. That is another issue that needs to be carefully looked at.

Senator STEVENS. Dr. Horn, my staff informs me that we are going to hear testimony that suggests that survey data is of greater social value for families as a whole and, therefore, that the written consent will have a negative impact on the usefulness of surveys. What is your comment about that?

Dr. HORN. There is no question that some surveys and questionnaires do have the potential for having a positive impact on the general well-being of families and children. But having stated that, it does not obviate the ethical requirement to ensure that prior to an individual child's participation, a child who does not have the competence to be able to decide for him or herself whether or not participation is in his or her best interests, someone makes a judgment that participation in that research is in the best interests of the child. The person most likely to have the child's best interests in mind in making that judgment is the child's parent.

So while it is true that some surveys may have some broad, general positive effect, that does not negate the need to ensure that the individual child's participation is consented to by someone competent to make that judgment and taking into account the individual child's best interest. If large numbers of parents fail to give that kind of consent, it would suggest to me that the researchers should examine whether or not what they are intending to ask of the children is contrary to the prevailing community standards or sensibilities.

Senator STEVENS. Art, as you know, I have six children. I can't quite understand some of the things that you have just told us. Our State law prohibits such inquiries without specific parental consent, and yet even in our situation, the requirement of the Federal officials because of the use of impact aid monies and other monies, they believe that they have the right to ignore our law?

Mr. MATHIAS. The schools, Mr. Chairman, as Lorraine Ferrell has testified—and she is vice chairman of the School Board of Anchorage—totally ignore the State statute under Title 14 of the State of Alaska, as well as Senator Grassley's amendment in Goals 2000 are not complied with or are ignored. And people are justifiably cynical. Something needs to change on this.

Senator STEVENS. Thank you very much.

Do you go outside the school environment, Mr. Knight, in your research? Do you go to the homes?

Mr. KNIGHT. Well, they come to us more often than not. We get calls from all over the country from people who are alarmed at this kind of thing happening to their children. A typical call might come from a parent in California who says, "Look, my son came home and said they asked him these questions," and the parent will say, "Well, I didn't hear anything about this." And that will send the parent on a circuitous route through the school bureaucracy to determine how this happened, and often the parent is told, "You are the only one who has really asked about this. You are the only one who has complained." And that leaves the parent feeling marooned. But they are not alone. Parents all over the country are waking up to the fact that their children are being targeted by people who are

using surveys and questionnaires as a way of acquainting their children with topics they would rather not acquaint the children with themselves, such as forms of sexuality.

When you ask a kid about 10 different ways to have sex, maybe the parent would rather convey that kind of information himself or herself, or not at all, particularly when the questioning concerns aberrant sexuality. That is the biggest complaint we get: That children have been asked, "Gee, when did you have same-sex relations, and how did you do it, and what did you do exactly?"

I mean, this is outrageous for children to be subjected to this kind of hazing in the form of research. And that is one reason we are so concerned about it.

Senator STEVENS. Thank you for the video. We will be glad to take it into our files. I will see if one of my staff doesn't have time to look at it.

Mr. KNIGHT. It comes with a 20-page booklet documenting everything in it, and we have corresponded with the Kinsey Institute, and they have recently broken their silence on some of the child sexuality data. Dr. Bancroft, the head of Kinsey, has admitted that there are files on this information. And all we are asking is that these files be opened to the public.

Senator STEVENS. Good. Very fine. We thank you all. You have come a long way, Art. I thank you.

Mr. MATHIAS. Thank you, Senator.

Senator STEVENS. We have to move along with this hearing, but I do want you to know, Mr. Hilton, we will take into account your suggestions, as well as Senator Grassley's. It is our intention to mark up this bill soon. Thank you very much.

Our next panel is Sally Katzen, Administrator of the Office of Information and Regulatory Affairs, the Office of Management and Budget; Felice Levine, Dr. Levine, of the American Sociological Association; Dr. Lloyd Johnston, Survey Research Center of the University of Michigan; and Sue Rusche, Executive Director of the National Families in Action.

Good morning, Ms. Katzen. You are the first witness. We are pleased to have you with us this morning. Won't you proceed?

TESTIMONY OF SALLY KATZEN, ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET

Ms. KATZEN. Thank you very much, Mr. Chairman. I appreciate very much the opportunity to appear this morning and present the administration's views on H.R. 1271. I have submitted written testimony which I hope will be included in the record.

Senator STEVENS. All the written testimony will be included in the record. We don't print them all, but if we print it, it will be included.

Ms. KATZEN. Thank you very much. I would like to use the time in my oral presentation to focus on a few important points. At the outset, I want to stress that this administration fully endorses and supports parental involvement and decisionmaking authority with respect to the participation of their children in research. That is not an issue. We also fully support and endorse parental notification of what is happening. That is not an issue. I believe those are

red herrings. We are not disputing the rights or the interests of the parents.

What is at issue for us is the bill's requirement for written—and I emphasize the term "written"—parental consent for federally funded research.

Now, there are many ways of obtaining parental consent. Written is one form. And in some circumstances—indeed in many circumstances—it may well be appropriate. But you can also have affirmative oral consent. That is another form. And there is passive consent, by which parents are informed of the research and are provided an opportunity to object, and failure to object is then implied consent.

The legitimacy of these other forms of consent is evidenced by their inclusion as part of the generally accepted social science research protocols, and they are part of the definition of what is known as "informed consent" in the literature.

To insist that all consent be written in virtually all circumstances can have a number of negative effects. These have been identified before, but I will just very briefly mention some of the most important ones. First—a reduced number of responses. Research indicates that as many as 50 percent of the parents will fail to give the written consent when first approached. If there is a follow-up, however, a very, very small percentage of that non-response actually has any objection to the survey or questionnaire. In the first instance it is usually due to a lack of time or concern: e.g. I have no problem with the survey, why should I return the form? I, too, am a parent of a child. I know the pieces of paper that come home in the backpack. And if I don't have strong feelings one way or the other, it can sit there.

Second, reduced responses lead to biased response. Again, research shows that the families least likely to respond are those that are highest at risk. If all parents went through every backpack, filled out every form, went to every PTA meeting, sat down and talked to the teachers, and went through the entire curriculum, I don't think we would be here discussing the need for the kind of research which we have in process for abused children, for neglected children, for runaway children, for homeless children, and for other children at risk. If we are restricted to written consent, we risk losing our ability to do research on these critical families.

Simply stated, the effect of this bill is to impair the validity and the reliability of important research. There are, as we have noted before, increased costs and increased burdens, particularly because schools are not allowed to give out information about parents' addresses and other kinds of personal information. As a result, school personnel will have to do the follow-up work here. This would be a significant burden for them.

As I said, there is ongoing Federal research that would be jeopardized. This research is important to be able to focus our intervention strategies, particularly at a time when funding is being limited, as it is in a number of Federal program areas. It is essential that we focus our resources on those who are most at risk, and to do that we need to have this kind of information.

Those who favor the legislation do so in the name of children, and I applaud that. I, too, am in favor of children, and the administration is in favor of children. It is important to recognize, however, that by being overprotective in the short run, you may do more harm in the long run. And I do not mean to be flip by using an analogy: Assume you do not want your child to be hurt when he is playing soccer, so you put on shin guards and elbow guards, and then a chest protector, a snowsuit, and finally wrap him in cellophane. He won't be injured but at some point he is immobilized and he can't play soccer.

We want parental involvement. We want parental decisionmaking. We want parental notification. But to insist on written consent and the cost that comes with it may jeopardize our ability to take care of our children.

Another argument advanced by those who support the legislation is that the government should not decide what research a child participates in and that researchers should not decide what research a child participates in. That is not what we are advocating. The rules that are in place are set by institutional review boards that consist of parents as well as local officials who are aware of, and sensitive to, local needs and local concerns. And the Federal regulations that are in place explicitly defer to local rules and State rules.

I am not familiar with the situation that you described in Alaska, but the Federal regulations specifically require deference to local needs.

Finally, for I see my time is running out, it is important to recognize that the problems of today's youth are very complex and they are changing. We cannot simply say we have enough research, we need no more. I would not want intervention strategies to be designed for my 13-year-old based on what it was like when I was 13—either the problems I faced or the resources available 40 years ago. We need to keep current with what today's children are experiencing and how they feel about it, if we hope to be at all effective.

Information is one of our most powerful tools to address the problems that plague our youth. Government programs, as well as educators and counselors on the front lines in their communities, rely on an accurate picture of youth practices and attitudes provided by this research. If we create road blocks to our understanding of what is happening to our youth today, we may well imperil the future and well-being of our children tomorrow.

I have been asked by the Department of Justice to indicate that they will be submitting a letter reflecting their views as well. I would be happy to answer any questions.

[The prepared statement of Ms. Katzen follows:]

PREPARED STATEMENT OF SALLY KATZEN

Good morning, Mr. Chairman and Members of the Committee. I am pleased to be here to discuss H.R. 1271, The Family Privacy Protection Act.

H.R. 1271, which passed the House earlier this year, was written with good intentions—to protect the privacy of families by requiring parental consent for certain types of information asked of minors in federally funded surveys and evaluations. In its present form, however—with its requirements for *written* consent, albeit with some exceptions to protect the health and safety of minors—the bill is likely to jeop-

ardize essential research that is the basis for our understanding of the risks faced by children in America today.

This administration fully endorses and supports parental involvement and decision-making authority with regard to the participation of their children in research. We believe that whenever possible, parents should be notified of, and given the opportunity to say "no" to, a research effort involving their children.

Social science research practice has long reinforced the policy that parents be contacted before interviewing minors, unless the health and safety of the child is threatened. Current Federal human subjects regulations (45 CFR Part 46, Subpart D) require that Institutional Review Boards review and approve most federally funded surveys to ensure that the necessary informed consent and privacy safeguards are in place. In addition, OMB's Office of Information and Regulatory Affairs carefully reviews agency surveys involving sensitive questions of minors to verify that appropriate parental consent is provided. In some instances written consent is appropriate; in other instances, passive consent—by which parents are informed of the research and provided an opportunity to object to the child's participation—is fully protective of the family's and the child's interests.

This administration strongly supports vital Federal research in the area of adolescent high risk behavior. Our ability to approach these issues sensibly, and to assess appropriate Federal intervention, if any, depends on our understanding of the extent of the problem and the dynamics that underlie teen decision-making and conduct. Information released this September from the National Household Survey on Drug Abuse revealed an alarming increase in marijuana drug use by youths. The Substance Abuse and Mental Health Services Administration will use this research to target the most at-risk youth identified by the survey in its prevention programs.

The Federal Government also sponsors important research on the well-being of minors in special circumstances, such as runaways, the homeless, and abused children. Gaining parental consent for these children would be difficult, if not impossible, particularly in those instances where parents cannot even be located. In the absence of research, intervention strategies would not have the benefit of information on characteristics of the population, sociological and demographic trends, or most importantly the attitudes and motivations of the children themselves.

It is also significant that with few exceptions, surveys and evaluations are conducted anonymously. In other words, no personal identifier information is collected and the identity of the minor and the family cannot be ascertained by others. With recent advances in technology, we are even more confident of our ability to protect a respondent's privacy.

Rather than relying on the carefully tailored and comprehensive review processes and procedures that are already in place, H.R. 1271 would impose an across-the-board requirement of written consent for all surveys, with very few exceptions. But, one size does not fit all circumstances when it comes to research on children.

In many instances, requiring written consent in all cases can have the following negative effects on research:

Reduced Responses. Research indicates that 50 percent of parents do not respond initially when their written permission is requested. The reasons they do not respond often include time constraints or simply forgetting to hand the form back to their child. When parents have no strong views one way or the other, the consent form is often perceived as mindless paperwork and may be ignored. Only a small percentage of these parents, when finally contacted, refuse permission for their children to be in the survey.

Increased Cost. RAND corporation research indicates that requiring written parental consent dramatically increases the cost of conducting a survey. The follow-up necessary, including phone calls, home visits and the extra time to get parents to return written consent forms, increases costs to $25 per response, compared to $1 for passive-consent surveys.

Increased Burden. The follow-up discussed above may require school personnel, rather than the researchers, to contact parents to encourage their written response because most schools are precluded from providing information about parents, their addresses or phone numbers to outsiders. Such a burden may prevent schools from participating in government research efforts. Parents may also have to be contacted repeatedly to return the written consent form, and some may find this an intrusion on their privacy.

Biased Responses. Parents respond differently to written consent requests, depending upon the situation and stability in their household. Economically at-risk families are less likely to respond than others. Moreover, research shows that children of parents who don't initially return signed forms are generally those at highest risk for behaviors such as dropping out of school and drug use. These are precisely the children that must be included in research of this nature.

One final concern is that if the term "program or activity" in this bill is construed in the same way as it has been under the Civil Rights Restoration Act of 1988, the adverse effects of H.R. 1271 could extend beyond research conducted with Federal funds to include research undertaken by States, cities, universities and other research institutions. As a result, these entities could either have their research activities limited or have to face significant additional costs.

Information is one of our most powerful tools to address the problems that plague our youth. Government programs, as well as educators and counselors on the front line in their communities, rely on an accurate picture of youth practices and attitudes provided by this research. If we create roadblocks to our understanding of what is happening to youth today, we may well imperil the future and well-being of our children tomorrow.

I commend you on having this hearing and beginning to explore what are very important issues. I would be happy to answer any questions. Thank you Mr. Chairman.

Senator STEVENS. Thank you. They are calling me to the other meeting, but I am constrained to tell you, I have put six kids through teen age, and I see no reason why they should ignore our laws and submit questions to our children that we haven't seen. I don't know what the burden is that you fear——

Ms. KATZEN. I do not in any way suggest that you should not be involved, that you should not be informed. Our objection is to the requirement for written consent.

Senator STEVENS. How are you going to get the consent? Unless a parent sees the questions that are going to be asked, how can you get the consent?

Ms. KATZEN. But there are various ways of getting it other than in writing. There is oral consent that can be obtained, for example through telephone call-in lines. And other forms of responses to information that can be sent home for parental notification.

If you look at the decennial census, for example, the follow-up to obtain written responses from initial non-responders is enormous. It isn't just a few dollars. It is a very significant step to track down those who have not responded, and the past research shows that the non-responders when ultimately contacted do not object to providing the information. They just haven't responded in writing. It is not as though 50 percent fail to send in a written response and then 50 percent say I don't want my child to do this.

Senator STEVENS. Thank you very much. I am sorry. I must move on. I am trying to—my substitute is the next item of business in the Commerce Committee, and when they call me, I am going to have to go. I am sorry.

Dr. Levine?

TESTIMONY OF FELICE J. LEVINE, PH.D., EXECUTIVE OFFICER, AMERICAN SOCIOLOGICAL ASSOCIATION

Dr. LEVINE. Thank you, Mr. Chairman, for the opportunity to come before your Committee to discuss an issue of great importance to American youth and their families. I am executive officer of the American Sociological Association. I am trained as a social psychologist and did research on children and youth. I spent 12 years as a program director at the National Science Foundation, including work on issues of human subjects protection, privacy, and confidentiality of data. Also, I am the mother of a 10-year-old daughter.

Today I am here on behalf of the Research and Privacy Coalition to testify in opposition to H.R. 1271. Our coalition is comprised of

a diverse group of organizations that represent parents, researchers, health care providers, educators, child advocates, and community groups. Our organizations strongly support parental involvement and informed parental consent. However, we are deeply concerned about the negative effects of H.R. 1271 on parents, children, and the Nation's ability to monitor and to understand crucial problems among its youth.

My formal testimony outlines a number of concerns that we have about H.R. 1271, and in the interest of time, I will highlight only three specific issues and how we recommend that they be addressed.

First, H.R. 1271 proposes a single, across-the-board, one-size-fits-all mechanism for obtaining parental consent that cannot in all instances be most effective for achieving that goal. The bill requires, as you have just heard today, a written statement from parents before a federally funded survey or questionnaire may be given to a minor in all instances whatsoever. This is not always the best way to ensure that parents are fully informed of the benefits and risks involved in their children's participation in a research survey. For example, a face-to-face interview or a telephone call might make much more sense or be more appropriate when illiteracy rates of parents are high.

We therefore suggest that decisions regarding the most appropriate way to obtain parental permission for the participation of minors in federally sponsored surveys requires a case-by-case attention to situation and local circumstances with Federal agencies, institutional review boards, and researchers held accountable for responsible implementation. Accountability is very important.

Second, H.R. 1271 flies in the face of the Committee's efforts via the Paperwork Reduction Act to decrease unnecessary paperwork throughout the government. It will mandate data collection burdens on parents and on schools and researchers that are unnecessary and costly, without consideration of what is really appropriate and efficient or even necessary in particular circumstances.

In school-based research, for example, the repeated follow-up contacts, the added notices, the multiple mailings impose substantial human and material costs. Added costs must be considered by this Committee. Studies have shown that only half of the parents, at most, will respond to an initial note requesting written permission for a child to participate in a Federal survey. Ultimately written consent is granted, but repeated follow-ups are necessary to obtain the signature.

We request that an analysis of the costs and bureaucratic burdens that H.R. 1271 will impose on parents, schools, and researchers be undertaken in assessing whether such legislation is appropriate.

Finally, H.R. 1271 will harm our ability to know how to help minors who engage in high-risk behaviors like smoking, drug abuse, and violence. Research shows that children whose parents do not return parental consent forms are at a higher risk for health and social problems. Therefore, we must ask, who is H.R. 1271 likely to hurt? Ultimately it will hurt the children whose pediatricians may not learn of a new drug being abused and even whose parents

may not know how to identify the early signs of problem drinking that they display.

Therefore, we urge the Committee to weigh the importance of having data for informed policy decisions regarding minors and assess the detrimental impact of this loss of knowledge. As the Committee deliberates on this bill, we ask you to consider the harmful effects of crippling our Nation's capacity to protect the most vulnerable among us, our children and youth.

In conclusion, let me emphasize that we share the Committee's interest in enhancing privacy protection for families and ensuring that families are notified and fully informed before their children can participate in research. We are confident that a bill can be crafted that strengthens parental consent without imposing a single congressional solution to a process that demands multiple approaches, flexibility, and judgment. And in that effort, our coalition is eager and available to assist in the process.

Thank you for your attention.

[The prepared statement of Dr. Levine follows:]

PREPARED STATEMENT OF FELICE J. LEVINE, PH.D.

SUMMARY POINTS

- H.R. 1271 assumes that a significant number of parents will object to the participation of their children in federally sponsored survey research. We urge the Committee to recognize that the vast majority of parents—including those who do not initially respond—support their children's participation in survey research.
- H.R. 1271 proposes a single mechanism for obtaining parental consent, thereby denying the opportunity to use more effective procedures. We suggest that decisions regarding the most appropriate means to obtain parental permission for the participation of minors in federally-sponsored surveys require case-by-case attention to situation and local circumstances—with Federal agencies, Institutional Review Boards, and researchers held accountable for responsible implementation.
- H.R. 1271 ignores the rights of children to assent or decline to answer a Federal survey or questionnaire. We suggest that a bill protecting the privacy and rights of parents should also protect the privacy and rights of children.
- H.R. 1271 flies in the face of this Committee's efforts via the Paper Reduction Act to decrease unnecessary paperwork throughout the government. We request that an analysis of the costs and bureaucratic burdens that H.R. 1271 will impose on parents, schools, and researchers be undertaken in assessing whether such legislation is appropriate.
- H.R. 1271 will have a serious negative impact on the quality of research findings involving minors. We recommend that the Committee weigh the importance of having valid data to inform policy decisions regarding minors and assess the detrimental impact of this loss in knowledge.
- H.R. 1271 will especially harm our ability to know how to help minors who engage in high risk behaviors like smoking, drug abuse, and violence. We urge the Committee to protect these important sources of information that enable you, and our communities, to do what is right for our children. As the Committee deliberates on this bill, we respectfully ask you to consider the harmful effects of crippling our Nation's capacity to protect the most vulnerable among us—our children and youth.
- In summary, the Research and Privacy Coalition believes parental permission can be obtained without damaging the viability of scientific questionnaires and surveys. These goals are not mutually exclusive. A bill can be crafted that strengthens parental consent without imposing a single Congressional solution in a process that demands multiple approaches, flexibility and judgment. We appreciate the attention the Committee is giving to this issue and are eager to assist in any way we can.

Introduction

Mr. Chairman, thank you for the opportunity to come before your Committee to discuss an issue of great importance to American youth and their families. I am Dr. Felice Levine, Executive Officer of the American Sociological Association. Trained as a social psychologist, I conducted research on children and youth, and spent twelve years as a Program Director at the National Science Foundation. In that context, I worked on such issues as human subjects protection, privacy, and confidentiality of data.

Today, I am here on behalf of the Research and Privacy Coalition, to testify in opposition to H.R. 1271, "The Family Privacy Protection Act of 1995." As indicated in the attachment, our coalition is comprised of a diverse group of organizations that represent parents, researchers, health care providers, educators, child advocates, and community groups dedicated to improving the health and quality of life of young Americans and their parents. Our organizations strongly support informed parental consent. However, we are deeply concerned about the negative effects of H.R. 1271 on parents, children, and the Nation's ability to monitor, understand, and address crucial problems among its youth. These concerns force us to oppose this legislation.

H.R. 1271 ostensibly enhances parental involvement and control over questions or information directed to a minor, but the bill actually undermines critical research on youth health behaviors and provides no significant additional protection to the privacy of families. Ironically, while this bill purports to help parents, it is more likely to harm their interests by jeopardizing their access to essential and valid information on high risk health behaviors such as drug and alcohol use, tobacco use, violence, and the like.

Before discussing the specific reasons our coalition opposes H.R. 1271, I will summarize briefly the legislative history of this bill.

History of Legislation

The roots of this proposed legislation originate in 1968 with the General Education Provisions Act (GEPA). GEPA, originally enacted as Title IV of the Elementary and Secondary Education Amendments of 1967, brought together in one document statutory provisions enacted during the previous 100 years that applied to Federal education programs. Since 1970, most major acts extending Federal education programs' authorization for appropriations have amended GEPA in some significant way. Three of those changes (the "Kemp amendment," 1974; the "Hatch amendment," 1978; and the "Grassley amendment," 1994) have significantly affected the "Protection of Pupils" section of GEPA.

The Kemp amendment required that parents of pupils participating in federally-assisted research projects be provided access to the relevant instructional materials. The Hatch amendment enhanced pupil protection by requiring prior consent of the pupil (if an adult or emancipated minor) or the pupil's parent/guardian and referred to specific areas of inquiry such as political affiliations; mental or psychological problems; sexual behavior or attitudes; illegal, anti-social, or "demeaning" behavior; "critical appraisals" of family members; privileged relationships; or income. The Grassley amendment expanded consent requirements to "any survey, analysis, or evaluation" that was federally-assisted, contained a lower threshold for triggering the consent requirements, and mandated written parental consent. The impact of these amendments was limited to federally-assisted programs funded by the Department of Education.

H.R. 1271, "The Family Privacy Protection Act of 1995," extends the jurisdiction of the 1994 Grassley amendment to all federally-funded government programs, and was originally introduced in the House as Title IV of H.R. 11, "The Family Reinforcement Act." It was referred to the Committee on Government Reform and Oversight. The Subcommittee on Government Management, Information, and Technology held a hearing on March 16, 1995, and Senator Charles Grassley of Iowa, Dr. Lloyd Johnston of the University of Michigan, Dr. Matthew Hilton of Utah, Ms. Sally Katzen of the Office of Management and Budget (OMB), and Mr. William T. Butz of the Bureau of the Census testified.

As a result of this testimony, Subcommittee Chairman Stephen Horn of California introduced an amendment in the form of a substitute to H.R. 11, and this amendment was introduced as H.R. 1271, "The Family Privacy Protection Act of 1995," on March 21, 1995. The provisions in this revised legislation include the requirement that active consent from a parent/guardian is required. The consent can be handled in various ways, including in writing. The mere notice of a survey is not enough to satisfy the consent requirement; there is a two-tier test necessary for consent. First, the parent/guardian needs to have disclosure about the survey or question-

naire. Second, the parent/guardian must have an opportunity to decline and notification must include a readily accessible method for the parent/guardian to exercise this option to decline. The legislation passed the Subcommittee unanimously by voice vote. The bill was marked-up by the Subcommittee on March 22, 1995.

The Government Reform and Oversight Committee met on March 23, 1995 to consider H.R. 1271. The bill as amended by the Subcommittee was favorably reported to the House unanimously by voice vote. We believe that the bill reported to the House by the Subcommittee and subsequently by the Committee was a fair and reasonable bill, accommodating concerns expressed by Federal agencies researchers, parents, and private citizens.

On April 4, 1995 as the full House considered H.R. 1271, Rep. Mark Souder of Indiana sponsored an amendment which reinstated an absolute requirement for written parental consent for participation of a minor. The House approved the legislation with this amendment, despite the unanimous recommendations from the Subcommittee and the Committee against an inflexible requirement of written consent from parents.

Concerns and Recommendations

Our concerns with H.R. 1271 are as follows:

(1) H.R. 1271 assumes that a significant number of parents will object to the participation of their children in federally sponsored survey research. We know of no data to support that assumption; in fact, the reverse is the case. In follow-up studies with parents who did not initially respond to a request for written permission, the overwhelming majority gave their consent for their children to participate. The same study showed that human nature to procrastinate, and not active refusal to participate, was the major reason parents did not return the permission forms.

We urge the Committee to recognize that the vast majority of parents—including those who do not initially respond—support their children's participation in survey research.

(2) H.R. 1271 proposes a single mechanism for obtaining parental consent, thereby denying the opportunity to use more effective procedures. The bill requires a written statement from parents before a federally-funded survey or questionnaire may be given to a minor. This is not always the best way to ensure that parents are fully informed of the benefits and risks involved in their child's participation in a research survey. For example, a face-to-face interview or a telephone call might be more appropriate, especially when parents are illiterate or less likely to understand the rights they have under current human subject protection rules.

The current standard used by the Federal Government is that "informed consent" must be obtained. We strongly affirm that Congress must emphasize "informed" and leave the specific means by which consent is obtained to fit the specific purposes of, and population in, any proposed study.

We suggest that decisions regarding the most appropriate means to obtain parental permission for the participation of minors in federally-sponsored surveys require case-by-case attention to situation and local circumstances—with Federal agencies, Institutional Review Boards, and researchers held accountable for responsible implementation.

Unfortunately the public is not sufficiently aware of the stringent procedures in place for federally supported research with regard to protection of human subjects. It may be useful at this point to review these procedures.

Federal guidelines and regulations (45 CFR 46) are working to assure that research subjects are informed of any risks and benefits of proposed research, and that they are given sufficient information about the research to decide whether to participate. The regulations specifically address the involvement of parents or guardians in research with children. Any proposed research project conducted by Federal grantees must be reviewed and approved by official Institutional Review Boards (IRBs) whose deliberations must consider such issues as consent, privacy, confidentiality, benefits, and risks. IRBs exist solely for the purpose of protecting the rights of all human subjects of research. These review boards include public members.

Research proposals must pass IRB review in order to be funded by a Federal agency. IRBs, as well as the regular peer review process at the Federal agency, are designed to ensure that a research plan involving young subjects includes a method to inform potential subjects and their parents about the study, and to obtain informed consent to the subject's participation. Reviewers require the researcher to have in place procedures assuring confidentiality and anonymity of respondents. Finally, every person who is asked to be a subject in a federally funded study has the right, and is given the opportunity, to decline to participate.

Who are the people who serve on these boards? The Regulations for the Protection of Human Subjects of Research established requirements concerning the membership of a local IRB, including: "each IRB shall have at least five members, with varying backgrounds . . . ;" it "shall be sufficiently qualified through . . . the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects;" if it "regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects;" "each IRB shall include at least one member whose primary concerns are in . . . nonscientific areas;" and "each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." As is apparent, these Federal regulations have recognized the necessity for research to be sensitive to local standards of acceptability, particularly when studies involve special vulnerable populations such as children.

In 1991, the 16 Federal agencies that conduct, support, or otherwise regulate human subjects research, adopted the Federal Policy for the Protection of Human Subjects, or the "Common Rule," as it is sometimes called. The virtually government-wide adoption of the Federal Policy made uniform the human subjects protection system in all relevant Federal departments and agencies. Unfortunately, several key provisions of H.R. 1271 are inconsistent with the basic principles of the Federal Policy, which for over two decades have been strengthened and enhanced to better ensure a model system for the ethical participation of human subjects in research.

(3) H.R. 1271 ignores the rights of children to assent or decline to answer a Federal survey or questionnaire. Current human subject rules protect subjects from participating in any Federal research against their will. It is important that children know they can refuse participation, free of social pressure or even subtle coercion.

We suggest that a bill protecting the privacy and rights of parents should also protect the privacy and rights of children.

(4) H.R. 1271 flies in the face of this Committee's efforts via the Paperwork Reduction Act to decrease unnecessary paperwork throughout the government. It will mandate data collection burdens on parents, schools, and researchers that are unnecessary and costly without consideration of what is really appropriate and efficient. In school-based research, for example, the repeated follow-up contacts, the added notices, the multiple mailings, impose substantial human and material costs, without the provision of resources to implement this requirement.

The added costs are an issue this Committee must consider. Studies have shown that only about half of parents, at most, will respond to an initial note requesting written permission for a child to participate in a Federal survey. Repeated follow-ups are necessary to achieve an acceptable rate of return of signed consent forms. A study by the Rand Corporation showed that the cost to achieve written consent for a single subject ranges from a low of $25 to a high of nearly $50. The cost of follow up just to obtain signed consent forms for a reasonably large study involving, say, 4,000 subjects, could add more than $100,000 to the cost of a study. To give some idea how to measure the import of that figure, consider that the average grant from the National Science Foundation for behavioral or social science research is about $50,000. An NSF grant likely could not cover the costs just of getting the consent forms returned, let alone doing the actual research and carrying out the subsequent analysis. Large national studies could disappear.

We request that an analysis of the costs and bureaucratic burdens that H.R. 1271 will impose on parents, schools, and researchers be undertaken in assessing whether such legislation is appropriate.

(5) H.R. 1271 will have a serious negative impact on the quality of research findings involving minors. Because of the low initial response rate of parents in returning written permission statements, an absolute Federal mandate requiring written permission from parents will result in insufficient sample sizes, thereby invalidating research findings. Studies of those who fail to respond to requests for written consent indicate that there is an over-representation among non-respondents of members of minority groups, low achievers, children with less well-educated parents, and most importantly, those at risk for engaging in problem behaviors. No study that excluded those children could claim to track accurately the health-damaging or health-enhancing behaviors of any community's young people. Simply put, with reduced sample size and biased responses, the Federal Government will not be able to meet its responsibility for informing the public about endemic problems.

We recommend that the Committee weigh the importance of having valid data to inform policy decisions regarding minors and assess the detrimental impact of this loss in knowledge.

(6) H.R. 1271 will especially harm our ability to know how to help minors who engage in high risk behaviors like smoking, drug abuse, and violence. Given that research has shown that children whose parents do not return parental consent forms are at a higher risk for health and social problems, we must ask: Who is H.R. 1271 likely to hurt? Ultimately, it will hurt the children whose pediatricians may not know of the emergence of a new drug of abuse, the children whose community policemen may not know how to spot the kids most at risk for gang membership, and the children whose parents will not know how early to discuss problem drinking with them. The survey research that H.R. 1271 would stifle or render ineffective is now relied on by policy makers, health care providers, parents, law enforcement officials, and all of us who care about children and youth.

We urge the Committee to protect these important sources of information that enable you, and our communities, to do what is right for our children. As the Committee deliberates on this bill, we respectfully ask you to consider the harmful effects of crippling our Nation's capacity to protect the most vulnerable among us—our children and youth.

Conclusion

In conclusion, let me emphasize that a win-win solution is both feasible and desirable. We share the interest of concerned legislators in fully informed parental consent, children's assent, and useful and meaningful information. We know that parental permission can be obtained without damaging the viability of scientific questionnaires and surveys. These goals are not mutually exclusive. A bill can be crafted that strengthens parental consent without imposing a single Congressional solution to a process that demands multiple approaches, flexibility, and judgment. In the coming weeks, your Committee will have the opportunity to amend the Family Privacy Protection Act. We appreciate the attention you are giving to this issue and are eager to assist in any way we can.

Letter from Undersigned Organizations

July 3, 1995

Dear Senator: The undersigned organizations wish to express their serious concerns about H.R. 1271, which passed the House of Representatives on April 4, 1995, and is now under consideration in the Senate Committee on Government Affairs. The bill, "The Family Privacy Protection Act," seeks to involve parents more directly in any federally funded "survey or questionnaire" conducted with minors. While this is an admirable goal, the bill has the potential to undermine current research on such important issues as substance abuse, violence, and adolescent pregnancy, without necessarily providing ANY additional protection to the privacy of families. Ironically, it is more likely to harm the interests of parents than to advance them.

H.R. 1271 requires *written* parental consent for any minor to participate in federally funded research that contains questions about "sensitive" areas named in the bill. Since half or more of all parents fail to return written consent forms which have been mailed to them, even though the great majority have no objection to their child being surveyed, the written response requirement produces very serious underrepresentation in the survey samples obtained, as well as serious bias. The bill does not acknowledge that there is already in place an extensive set of regulations to protect human subjects in federally funded research. Before a research project can even be submitted to a Federal funding agency, an Institutional Review Board (IRB) must approve the research protocol, the procedures for assuring the confidentiality of the subjects, and must weigh the risks and benefits of such research. The IRB stringently reviews any research protocol involving children or adolescents. It may require written parental consent, or if it judges the research to be of minimal risk, it may allow another consent procedure. But the standard used by the IRB is for the "informed consent" of all participants. For example, an IRB might determine that a research project with children whose parents had low literacy skills could use a different method of consent than a written form. That flexibility would be lost under the provisions of H.R. 1271.

In addition to the system of IRB protection, most professional organizations with a scientific mission develop and adhere to stringent codes of research ethics. These codes seek to protect research subjects (and, in the case of minors, their families) from any risks associated with participation in research.

Clearly, survey research provides valuable information relied upon by educators, families, policymakers, public health professionals, health care providers, and private sector groups. It is difficult to imagine trying to respond to the many threats facing our youth without accurate, reliable survey data. One effect, however, of H.R. 1271 may be that a number of nationwide surveys will not be able to continue. Obtaining a representative sample of adolescents may in some cases be too difficult for schools or researchers to manage, or be too costly.

H.R. 1271 may affect the ability of groups to conduct evaluations of Federal programs already in place. In addition, longitudinal research (in which the same participants are reinterviewed after a period of time) may become impossible to conduct if written consent from the same sample were required with each interview. Much of the first-rate research on substance abuse now conducted in the schools would be affected.

It is essential that these concerns be addressed before this bill reaches the Senate floor. The undersigned organizations urge that the Senate Committee on Governmental Affairs hold a hearing on this measure, and allow scientists with expertise on research with children and other knowledgeable experts to testify.

Sincerely yours,

Advocates for Youth
Alan Guttmacher Institute
American Academy of Pediatrics
American Educational Research Association
American Pediatric Society
American Psychological Association
American Psychological Society
American Sociological Association
Association of Medical School Pediatric Department Chairmen
Association of Population Centers
Association of Schools of Public Health
Association of State and Territorial Health Officials
Center for Science in the Public Interest
Community Anti-Drug Coalition of America
Consortium of Social Science Associations
DARE America
Federation of Behavioral, Psychological & Cognitive Sciences
Girls, Incorporated
National Association for Native American Children of Alcoholics
National Family Partnership
National Family Planning and Reproductive Health Association
National Hispanic Latino Community Prevention Network
National Mental Health Association
National Parents' Resource Institute for Drug Education (PRIDE)
National Network for Youth
Population Association of America
Prevention, Intervention and Treatment Coalition for Health (PITCH)
Society for Adolescent Medicine
Society of Behavioral Medicine
Society for Pediatric Research
Society for the Psychological Study of Social Issues
Society for Research on Adolescence
Society for Research in Child Development
Spanish Addiction Resources and Training
The Entertainment Industries Council

RESEARCH AND PRIVACY COALITION

The following members of the Research and Privacy Coalition wish to endorse the statement of Dr. Felice Levine before the Senate Committee on Governmental Affairs, November 9, 1995:

Advocates for Youth
AIDS Policy Center for Children, Youth and Families
American Education Research Association
American Pediatric Society
American Psychological Association
American Psychological Society
American Sociological Association

Association of Medical School Pediatric Department Chairmen
Association of Population Centers
Community Anti-Drug Coalitions of America
Consortium of Social Science Associations
Federation of Behavioral, Psychological and Cognitive Sciences
Institute for the Advancement of Social Work Research
National Association of School Psychologists
National Mental Health Association
Northwestern University
Population Association of America
Society for Adolescent Medicine
Society of Behavioral Medicine
Society for Pediatric Research
Society for Research in Child Development

ARTICLE FROM THE CHRONICLE OF HIGHER EDUCATION

(Section 2) Opinion & Arts—November 10, 1995

CONSENT FOR RESEARCH ON CHILDREN

By Felice J. Levine

Should parents know if their children are being asked to participate in surveys to answer research questionnaires financed by the Federal Government? Should parents be given the opportunity to forbid their children's participation if they deem the research inappropriate?

Most Americans would respond with an unequivocal Yes to both questions. So, too, would the overwhelming majority of social scientists and researchers who conduct surveys or other studies. And, in fact, current Federal regulations clearly affirm the right of parents to consent to their children's participation in federally supported research—regulations that have been in effect since 1974.

Despite this, in April the House of Representatives passed the Family Privacy Protection Act, an ill-advised effort to impose rigid guidelines on how parental permission should be obtained. The bill requires that, in all cases, parents must give written consent before their children can participate in research. The Senate Committee on Governmental Affairs has scheduled a hearing this week on the legislation.

On the surface, requiring written permission might not seem to be a major change. But if the Senate follows the House's lead and adopts such a requirement, the legislation will curtail and bias research on issues that are fundamental to the well-being of our children.

Unfortunately, the Senate might be inclined to go along with the House. The provision was one of the pledges included in the Republicans' original Contract With America, and last year Congress approved a similar requirement advanced by Sen. Charles Grassley, Republican of Iowa, for research financed by the Department of Education.

Federal regulations for protecting human research subjects now require a child's agreement to participate in research as well as parental consent, which often is documented by obtaining written consent. But the institutional review boards at colleges, universities, and other organizations, which screen and approve research proposals before they receive financial support, can mandate or approve other procedures that may be more appropriate for a particular research project or group of subjects, in order to obtain truly informed consent, protect privacy, and minimize risk to research subjects.

For example, face-to-face meetings may be used to obtain consent if parents are not literate or do not read English very well. When researchers conduct telephone surveys, the interviewers frequently telephone parents and obtain and document their consent before talking to the children. In rare cases, essential research would be impossible if written consent were required; think, for example, of a proposed survey of runaway children, who might refuse to identify their parents.

Essentially, then written permission makes sense in some cases, but not in all. Several recent studies have documented the fact that parents often fail to sign and return written consent forms, not because they object to their children's participation in research, but simply because they do not have the time or take the time to read the forms and sign them. Moreover, according to recent research by the Rand Corporation, such parents are more likely than the rest to have children at risk. In short, requiring written permission in certain instances would reduce the number

of respondents, bias results, and give less information about the very youths who may most need attention.

Parents have both a right to consent and a right to know about issues affecting their children. But by imposing a single mechanism for obtaining consent, the House legislation would eliminate all latitude for determining, case by case, what is most appropriate to particular studies, situations, or groups of subjects. And, with less-reliable survey research, parents, policy makers, and the public will know less—a lot less—about the problems, health dangers, and challenges our children face.

In July, the University of Michigan Survey Research Center released findings from its acclaimed National High School Survey, which has tracked the behavior of students for 21 years. The center reported that, contrary to some public pronouncements, use of illicit drugs among students was on the rise. The study revealed a sharp increase in the use of marijuana by teen-agers and showed that such use is leading to an increase in the number willing to try other drugs. The survey also found an alarming increase in the number of young people smoking cigarettes. The report concluded that "the implication of this increase in adolescent smoking for the country's future rates of disease, early death, disrupted families, worker productivity, and health-care costs cannot be overestimated. . . . Cigarettes will kill far more of today's children than all other drugs combined, including alcohol. But because these consequences do not emerge for a few decades, we seem to be much less concerned about them. If cigarette smoking killed quickly, like drunk driving does, the country would be treating the current rates of adolescent smoking as an extreme emergency."

This is an alarming report, but it also represents the type of information that parents have a right to know, and that public officials have an obligation to gather if they are to enact meaningful and effective public policy. To obtain parental consent in that survey, school principals sent parents letters telling them where they should call or write if they did not want their children to participate.

The director of the survey told the House Committee, when it was considering the Family Privacy Protection Act, that a requirement for written permission would severely damage the credibility of the National High School Survey, because "parents fail to respond in writing even though they have no objection to their children's participation." He noted that schools did not have the resources to undertake expensive follow-up efforts to obtain consent. The net result of requiring written parental consent would be, he said, "less-representative, poorer-quality research at considerably higher cost, with overburdened schools shouldering more burden than before, and parents being bothered more. A number of studies may simply yield unusable results."

Such concerns have led about 35 science, education, public-health, and parent organizations to form a coalition to oppose an absolute requirement for written consent. They support the right of parents to consent, and they endorse the right of a young person to refuse to participate in a study, an objective not addressed in the Family Privacy Protection Act.

In the form in which it was reported by the House Committee on Government Reform and Oversight in late March, the Family Privacy Protection Act, instead of fixing on form over substance, emphasized the need for meaningful informed consent by parents and the need to give them an opportunity to decline to let their children participate. It also prohibited children from participating in a broad range of federally sponsored surveys or questionnaires—without the prior consent of at least one parent or guardian—if the research instruments included questions on such sensitive issues as psychological problems, illegal behavior, political beliefs, or sexual attitudes. The bill applied to federally financed surveys, whether undertaken by an agency of government or by researchers using Federal money.

The Committee's bill, in effect, strengthened existing stringent Federal regulations intended to protect children's participation in federally financed research. The problems associated with a uniform requirement for parents' written consent had been aired by scholars and policy makers during the House Committee's consideration of the measure. And the Committee decided to drop such a requirement precisely because of the potential problems the opponents outlined.

But then, appealing to general concerns about "family privacy" and the role of parents in making decisions about their children, proponents of written consent managed to reverse the Committee's position on the House floor, winning approval of an amendment that requires written parental consent.

Certainly a requirement for written consent from parents of all children involved in research surveys will increase the costs and the workload of researchers and often of schools. But the more basic and compelling reason why the Senate should drop the requirement is that parents and the public need access to reliable informa-

tion to alert them when their children face serious social or health problems. Such information can lead to public-policy measures that provide a safer and more secure environment for our youth. Parents also need to know to what degree families are coping or failing to cope with the stresses of modern life, and to understand the possible implications for their own families. Collection of reliable survey data that can meet those needs will be hampered, and research results skewed, if every parent must submit a written consent form.

Where do we go from here? In the next few weeks, the Senate Committee on Governmental Affairs has the chance to drop the requirement for written parental consent in the Family Privacy Protection Act. Scholars, researchers, and families must seize the opportunity to explain why the Committee should do just that.

Felice J. Levine is executive officer of the American Sociological Association.

Senator STEVENS. I wish I had more time, Doctor. I would like to go into questions.

Dr. Johnston?

TESTIMONY OF LLOYD D. JOHNSTON, PH.D., RESEARCH SCIENTIST AND PROGRAM DIRECTOR, SURVEY RESEARCH CENTER, UNIVERSITY OF MICHIGAN

Dr. JOHNSTON. Yes, good morning, Mr. Chairman, and thank you for the opportunity to testify. I am a research scientist and program director at the University of Michigan Survey Research Center where I have studied problems of American youth for over 30 years, the last 21 as principal investigator of the Monitoring the Future Study, which I will refer to in a moment.

I should also add, perhaps, that I have published some 30 books and monographs and 60 or 70 articles on the subjects of problems among our youth, and it is a subject about which I care deeply. It is not just an academic interest, as they say.

Let me start by saying that I am very, very concerned about the impact of this bill as currently written on the range of activities that are affected and the resultant ability we will have both to monitor the problems that our youth are having, and to understand those problems. And this concern is widely shared in the scientific and policy communities as you are beginning to see. There is very great concern about this among people who do care about children.

In my short time here, I will try to explain why I think that this particular written consent requirement will have such a devastating impact, how great I think the costs are, and what alternative methods might be considered.

You have already heard some comments about alternative methods. I might mention what we do on our own surveys of roughly 50,000 students a year, and we have been doing it for the past 4 years. We provide advance notification to the parents well in advance of the survey, 2 or 3 weeks in advance, with a first-class letter. It is usually from the principal to the parents because we are not allowed to have the names and addresses or phone numbers of the parents. And it gives a short description of the study and a simple means for the parent to decline. That simple means may be a local phone call to some office of the school saying they don't want their child to participate in the study, or a letter or postcard that can be returned. The latter would be pre-stamped and pre-addressed.

I think this alternative mechanism is a reasonable one, a reasonable compromise between the conflicting needs that are involved here. It virtually guarantees that the parents will know about the survey, be informed about it, have an opportunity to ask questions if they wish; and it guarantees they will have a chance to decline.

I should add that our experience is that in surveys like this one, which already have passed all the rigorous reviews and hurdles that exist for federally financed research, we get very low rates of parental refusal, on the order of 1 or 2 percent in the case of our own study. It is sometimes 3 or 4 percent, depending on the subject matter, in some other studies. These are very low proportions of parents who really object to their children being in most of these studies.

I have provided a literature review in my written testimony, which I hope that you will put in the record. In it you can see that a number of people who have used a written consent procedure, including ourselves in one component of our own study, get response rates from the youngsters that are in the 50 to 60 percent response-rate range, not the usual 95 to 99 percent response-rate range. These really are response rates which are unusable scientifically.

We know from further analysis, and from finding in the literature, that the parents of youngsters who are from low-income backgrounds, from minority groups, and at risk for dropping out of school, and a whole range of other problems, are particularly unlikely to answer their mail. We further know that these are not people who mean to decline the participation of their children, because several studies have had phone follow-ups of these parents and found that, in fact, they simply are not answering their mail. Indeed, we find that only about 1 percent say they don't want their children involved once an answer is finally received.

The research that would be affected by this bill is very broad. I think the telephone surveys of young people would be wiped out. This would include, for example, the National Crime Victimization Survey of Youth. In-school surveys which provide some of the most valid and accurate data on sensitive behaviors like drug use will either be seriously damaged or eliminated, and this will be a major loss. It will include national surveys like our own, the many State surveys which use pass-through monies from the Federal Government, and thousands of local assessments which are done at the initiative of local school systems and communities. I have worked with a number of those, and they use pass-through monies as well.

I might also mention that Congress has mandated evaluation studies of many programs that it funds. Those will be seriously damaged, and there probably are hundreds of studies currently funded and underway which, again will be seriously damaged.

I see that my time is running low, so——

Senator STEVENS. Yes. I am sorry to say I have been called to the other committee.

[The prepared statement of Dr. Johnston follows:]

PREPARED STATEMENT OF LLOYD D. JOHNSTON, PH.D.

Mr. Chairman and Members of the Committee, I greatly appreciate the opportunity to testify before you on the Family Privacy Protection Act of 1995, H.R. 1271.

Although, on its face this modest piece of legislation seems reasonable, and perhaps even non-controversial, I can assure you that if enacted as originally written, it will have disastrous consequences for the country's ability to track and to understand some of the most important problems facing American young people today.

Perhaps I should begin with a few words about my background. My experience comes from conducting national surveys on a host of problems among American young people for nearly 30 years—the past 21 as the principal investigator of the Monitoring the Future Study, a series of annual national surveys supported primarily by the National Institutes of Health and carried out at the University of Michigan's Survey Research Center. I have written extensively on youth problems and served on many policy advisory groups, including the National Commission for Drug-Free Schools, the National Advisory Council on Drug Abuse, and the White House Conference for a Drug-Free America. I also chair one committee and serve on another for the National Education Goals Panel.

What Is at Risk?

This study has provided the past six administrations, beginning with President Richard Nixon, the most reliable information available on levels and trends in licit and illicit drug use among young people, which for much of our recent history constituted one of the Nation's chief domestic concerns. The study has called the attention of parents, policy makers, and the citizenry as a whole to the sharp increase in the use of marijuana and other drugs in the late 1970's, the increase in cocaine use into the early 1980's, the unnoticed increase in inhalant use in the late 1980's and into the 1990's, and the renewed increase in the use of marijuana and a number of other drugs in the last four years (following a sustained period of decline for many drugs). The study has also demonstrated the great importance of perceived risks for the user, and peer norms against use, as determinants of the rise and fall in the use of these drugs—a knowledge breakthrough that has helped to enhance our understanding and to guide the Nation's efforts to deal with these serious problems among our youth.

I can tell you with certainty that the consumers of this information and knowledge include a great many parents, parent groups, community coalitions, educators, commissions, nongovernmental organizations concerned with educating parents (such as the National Partnership for a Drug-Free America [PDFA]), and legislators and other policy makers at both the Federal and State levels. In just the last two years the study's findings have prompted a marijuana prevention initiative at both the PDFA and the Department of Health and Human Services (DHHS). It also stimulated an inhalant prevention initiative at the PDFA (that is, a national public education advertising campaign).

A number of commentators have observed that the problems our children experience today are of a different order of seriousness than those confronted in earlier generations. We no longer worry about children sticking gum to the bottom of their desks or taking water guns to school. Now we worry about real guns in school, children shooting others or being shot, youngsters using dangerous drugs, and perhaps contracting deadly diseases like AIDS. Childhood has become a more dangerous time in America, and parenthood, education, and policymaking have become more difficult tasks. We all need more light, more understanding, of these subjects in order to better protect our youngsters who are facing these hazards, and to better prepare them to make responsible choices when temptation and/or peer pressure present themselves.

A number of studies play an ongoing role in enlarging and updating our understanding of these problems. Monitoring the Future, of course, is the example most familiar to me. It provides up-to-date information every year on the following: usage levels for marijuana, cocaine, heroin, and a host of other illicit drugs, as well as alcohol and cigarettes; attitudes, beliefs, and perceived availability in relation to all of these drugs; reasons for using, quitting, and abstaining from the use of these drugs; problems experienced as a result of their use; rates of drunk driving and exposure to drunk driving as a passenger; seat belt use; frequency of carrying guns or other weapons to school; concerns about safety at school or on the way to or from school; frequency of cutting school for fear of physical harm; frequency and nature of victimization at school and of victimization more generally; frequency of acts of interpersonal aggression; attitudes about school and about drug prevention programs to which students have been exposed; and so on. I enumerate this long list of subjects to illustrate the range of problems today's children and families face, as well as to show the types of information that will be lost if the provisions in the Family Privacy Protection Act are enacted. At present, this one study provides key information for the accomplishment of national goals in the areas of drug abuse, education, and health. It provides most of the national measures for tracking the

accomplishment of Goal 7 of the National Education Goals for the Year 2000—"safe, disciplined, and alcohol—and drug-free schools." It also provides measures for some of the health goals for Healthy People 2000 and some of the key information for the National Strategy on Drug Abuse, which is Congressionally mandated and submitted annually to Congress by the White House Office of National Drug Control Policy (ONDCP). In fact, I find myself in the ironic position of having participated in a meeting last week in which the ONDCP was seeking advice on how best to meet the expanded Congressional demands for information on drug use in the country, contained in legislation reauthorizing the ONDCP, and then today meeting with a Congressional Committee on a bill that without question will hobble the ability of this administration and all future administrations to report just such information.

The Central Problem with the Bill

To require parental review before a youngster participates in research on a sensitive subject seems a reasonable requirement to most people, I assume—it does to me. And I further assume that the critical elements to parental review are providing parents (a) advance notification and description of the research and (b) an opportunity to decline their child's participation. The critical flaw in the present bill is not that it gives expression to these principles but rather in the specific way that it insists that they be expressed.

Requiring researchers to secure written parental permission in advance makes one survey into two surveys, because parents must first be surveyed to obtain their written permission, and only then can the students be surveyed. This might be acceptable, assuming that the substantially greater costs to the government were tolerable, were it not for the fact that the non-response rates from parents are debilitatingly high. I say debilitatingly, because the resultant response rates for the young people would be so low in most cases as to render the data useless at worst, highly misleading at best.

I attach—and request entry into the record along with my testimony—a short synopsis of the literature on the effects of written consent. This was prepared for these hearings by my colleague, Dr. Patrick O'Malley, and me. It begins with a report of our own experience using a written consent procedure for a part of the Monitoring the Future Study in which we conducted a mail follow-up survey of a national sample of eighth grade students. Because it is based on a national sample, the results should be highly generalizable to other studies of the youth population.

What this review shows is that when research studies have been required to secure written parental consent in order to gather survey data from minors (who are almost always teenagers), three things happen. First, the attained response rates are driven down to the 50 percent to 60 percent range or below, from what otherwise would have been the 95 percent to 99 percent range for in-school surveys. Second, those young people who do participate are highly unrepresentative of the population sampled, because the parents of the less privileged, minorities, and more risk-prone youngsters are much less likely to answer their mail than others. The third consequence is that the costs of conducting the survey go up very substantially, precisely because what started out as one survey of youth ends up to be two surveys (of parents and youth), with all the attendant costs of sending out the instruments and following up by mail, phone, etc., to try to secure an acceptable response rate from the parents.

The fact that 40 percent to 50 percent of the parents do not answer by mail should not be interpreted as a refusal, as the written consent method forces us to do, because follow-up studies by phone have shown that the vast majority of non-responding parents are quite willing to give their approval, and that in the end only 1 percent to 2 percent of all parents really intended to decline. Neither does the much higher parental non-response rates observed in the highest-risk segment of the population indicate a greater intent to decline on their part. In our own study, reviewed in the attachment, only 1 percent of the parents of high-risk students ultimately indicated their refusal after extensive follow-ups were conducted to locate them by telephone.

In sum, the introduction of a written parental consent requirement—as contrasted to advance notification and description with a convenient method for the parent to decline—will result in virtually unusable data from practically all in-school and phone surveys of youth, including some important ongoing series like our own. (Household surveys would be least affected because the interviewer is already at the home, usually speaking with one of the parents.) Because household surveys are vastly more expensive than in-school or telephone surveys (averaging $300 to $500 per respondent), and because they have proven to be one of the least valid approaches for gathering data from youth on sensitive behaviors, they really cannot make up for the loss of in-school and telephone surveys. In-school surveys have

proven to be the most effective at gathering valid data on sensitive subjects like illicit drug use, even use of legal drugs like alcohol and tobacco. It appears that in the home setting minors are less comfortable admitting to behaviors of which their parents would disapprove, even when the parent(s) cannot hear them.

I should also note that there are many federally funded, ongoing multi-year studies that are likely to be rendered unusable by the introduction of a written parental consent requirement, because their follow-up surveys will obtain much lower follow-up response rates than they did in the baseline surveys, which already have been conducted; and, of course, the high-risk young people will be systematically lost in the follow-ups. This is not a minor impact. I would venture to say that there are hundreds of on-going studies out there under the sponsorship of Labor, Education, HHS (NIH, SAMSHA, CDC, etc.), NSF, and so on. Many are evaluations of prevention and other intervention programs across a host of areas. Our ability to learn about the efficacy of these programs will be seriously compromised by the currently proposed legislation.

Alternative Solutions

I stated earlier that I endorse the principles of informed parental consent: with parental notification and information about a survey provided well in advance, and an opportunity for parents or guardians to decline their child's participation using some convenient response mechanism. That response mechanism could be a local call to the principal's office (or some other designated person in the school), returning a pre-addressed, stamped letter or postcard declining participation, or calling a designated 800 number maintained by the researchers. Remember that virtually all federally conducted or sponsored studies already have been screened by Federal research review committees, Federal agency personnel, Institutional Review Boards (IRBs) for the protection of human subjects, and by the school and/or school system research review committee. For that very small fraction of parents who object to their child participating in research, even after it has gone through all of these safeguards, there still could be a nearly foolproof mechanism by which they could be informed about the survey and have plenty of opportunity to decline. It would simply require mailing notification letters to the home and, for that 1 percent or 2 percent who really wish to decline, for them to make a local phone call or drop a prepaid postcard in the mail making their wishes known.

In my testimony on this bill before the House Subcommittee on Government Reform and Oversight (March 16, 1995) I reviewed the strengths and weaknesses of several logical alternatives for securing informed parental consent. I will not repeat that information here; suffice it to say that methods that do not require written consent have far fewer costs and more benefits. The Members of that Subcommittee agreed, and made some judicious changes during markup—in particular, by deleting the requirement that parental consent has to be in writing. I hope that this Committee will do likewise.

Summary and Conclusion

Reducing the usefulness and accuracy of research results on the problems of youth hurts just about everyone in society—in particular parents and their children, whom this bill purports to protects. Society's institutions will be rendered less effective at recognizing and responding effectively to the problems young people experience. Parents will be less aware of the scale and nature of the risks their children face, and less informed about the risk factors and symptoms for which they should be watching.

Schools will be burdened more heavily at a time when they already are overworked, because they would become responsible for securing the written consent forms, since they are prohibited from giving out the names, addresses, and phone numbers of the parents, even to researchers. (Inner-city schools, whose resources are stretched the most, will be burdened the most by this legislation, because the parents of those children are among those least likely to respond to mailed request for consent.)

Researchers, of course, will be burdened with one more layer of bureaucratic requirements on top of so many layers that it begins to make regulations on small business—which this Congress is trying to reduce—look mild.

Additionally, the Federal Government will be raising the cost of the research it buys while simultaneously and severely diminishing the value of the research product it receives.

As the leader of a parent resource organization commented to me this week, a vote for this bill is a vote against the family. I would add that a vote for this bill is also a vote for more government regulation, higher costs, and a much poorer research product.

Indeed, the only logical reason I can think of to vote for this bill is if one's real intent is to kill off effective research on the problems of our young people; and that would be a step back toward darkness. As I have tried to suggest, the legitimate concerns of parents—even that very small fraction who seem so very concerned about these things—can be met without such a step backward. The full range of parents' concerns and needs can be met quite nicely using alternative methods to the very rigid one proposed here.

REFERENCES ON THE EFFECTS OF A WRITTEN PARENTAL CONSENT REQUIREMENT

Reference: Special Analyses from the Monitoring the Future Study. See Johnston, L.D., O'Malley, P.M., & Bachman, J.G. (1994). *National survey results on drug use from the Monitoring the Future study, 1975–1993. Volume I: Secondary school students* (DHHS Publication No. (NIH) 94–3809) and Volume II: College students and young adults (DHHS Publication No. (NIH) 94–3810). Rockville, MD: National Institute on Drug Abuse.

One national survey, Monitoring the Future, which has been surveying 12th grade students for over 20 years (and 8th and 10th grade students for the past 5 years) generated some estimates of the effects of active consent. The study surveys 50,000 children in 420 schools per year.

A portion of this annual national survey seeks active parental consent for its panel of students being followed up by mail at their home address (two years after they were surveyed in school while in 8th and 10th grades). It provides evidence of the effects of written consent because written consent of the parent is sought first, and then oral consent by telephone is sought from those not responding.

It is a "best case scenario" of what would happen if written consent were sought at the initial school contact, because in this case the parent knows that (a) the child already participated in the survey at school, giving it some legitimization, and (b) the child will be paid $20 for completing a 40-minute questionnaire.

Nevertheless, fewer than half of the parents (48.7 percent, 1993 and 1994 combined) returned a signed postcard, which is stamped and self-addressed. The remainder were contacted by telephone. Another 35 percent provided oral consent by telephone, while only about 1 percent refused. (Some families could not be located due to the 2-year time lag from the initial survey.)

Considerable bias would have resulted in the obtained sample had only those giving written consent been available for analysis. Four strata had been used in sampling these follow-up panels, defined on their risk for dropping out of school. The parental response rate by mail was about 30 percentage points higher in the lowest risk stratum than in the highest risk stratum. The stratum with the highest risk for dropping out (and therefore the highest risk on a number of other dimensions of problem behavior, including drug use, crime, violence, premature sexual behavior, etc.) had a parental response rate by postcard of only 30 percent. However, another 44 percent provided verbal consent by telephone and, again, only 1 percent refused. (Thus, the much lower initial parental non-response rate for this high-risk group did not reflect any greater intent to decline.)

One East Coast inner-city school required that the study use active written consent for the in-school portion of the survey. (Usually, a procedure involving prior notification with explicit refusal is used in this study.) A sample of 100 parents was chosen, but only 17 returned the consent form, so the school had to be eliminated from the study on the grounds that the 17 were highly atypical of the school's population.

Reference: Kandel, DB & Davies, M (1991). Decline in the use of illicit drugs by high school students in New York State: Comparison with national data. *American Journal of Public Health,* 81:1064–1067. See also a final report: Kandel, DB, Davies, M, & Davis, BL (1990). New York State Youth Survey: Epidemiological Survey of Drug Use among New York State Junior and Senior High School Students. New York State Office of Mental Health, New York.

In a survey conducted under funding from New York State, some schools required active parental consent before allowing their students to participate in the survey. The student participation rate for schools requiring active parental consent was only 67.8 percent compared to over 95 percent for schools not requiring active consent.

One school had to be dropped because only 20 of 224 students returned signed parental consent forms.

Student participation was lowest in predominantly non-white schools that required active parental consent. Of 15 schools in New York City that required active parental consent, the 11 predominantly non-white averaged 55.1 percent completion rate, compared to the 4 predominantly white schools, which averaged 79.5 percent.

Reference: J. S. Brook, Ed.D (Personal communication)

One NIH-funded researcher attempted to study 1,600 12 to 17 year olds in Harlem, NYC. Only about 800 (50 percent) of parents returned written consent forms. The researchers began telephone follow-ups, following Institutional Review Board requirements. Of the first 400 parents they contacted, approximately 98 percent agreed verbally to allow their children to participate in the study (they were not required to send in written forms).

(At that point, the Institutional Review Board agreed to allow a procedure of advance notification with explicit refusal only, since it was clear that very few parents in fact objected to the study, and that the study would be jeopardized because of the difficulty in reaching the remaining parents, some of whom did not have telephones.)

Reference: Dent CW, Galaif J, Sussman S, Stacy A, Burtun D, Flay BR (1993). Demographic, psychosocial, and behavioral differences in samples of actively and passively consented adolescents. *Addictive Behaviors,* 28:51–56.

The conclusion was that "those children who are omitted from a research study because of lack of action on the part of the parent are at higher risk for a number of health and social problems."

The sample recruited by active parental consent had fewer minorities, fewer persons who were dissatisfied with school, fewer persons whose parents were of lower educational levels and fewer cigarette smokers. Students whose parents failed to respond were less likely to live with both parents, more likely to be latch-key children, higher in risk taking, lower in self esteem, and lower in assertiveness.

Reference: Ellickson, PL, & Hawes, JA (1989). An assessment of active versus passive methods for obtaining parental consent. *Evaluation Review,* 13, 45–55.

These researchers concluded that nonresponse to passive consent typically reflected conscious parental approval; nonresponse to active consent generally signified latent consent, not a deliberate refusal; vigorous retrieval methods substantially raised active consent response rates, but at a high cost in time and money.

Reference: Keamey, KA, Hopkins, RH, Mauss, AL, & Weisheit, RA (1983). Sample bias resulting from a requirement for written parental consent. *Public Opinion Quarterly,* 47, 96–102.

Data were collected in the 1978–1979 school year; 1,618 children in grades 4 through 12 in Seattle and Portland areas participated. Explicit parental consent requirement produced a response rate of 51 percent, and a sample biased on race and test scores.

The written consent procedure produced a sample that was approximately half the size of the eligible population and over-represented white students while under-representing blacks and Asian Americans.

Reference: Leuptow, L, Mueller, SA, Hammes, RR, & Master, LS (1977). The impact of informed consent regulations on response rate and response bias. *Sociological Methods & Research,* 6, 183–204.

High school seniors were surveyed on nonsensitive subjects. Consent sharply reduced response rates relative to a 1964 survey. "While 69.7 percent of the adult students [18 years old or older], who could give their own consent, participated in the study, only 42.4 percent of the minors who required parental consent were included." (p 188) (Overall response rates were lower than normal because of some administrative complexities involving code numbers)

Reference: Moberg, DP, & Piper, DL (1990). Obtaining active parental consent via telephone in adolescent substance abuse prevention research. *Evaluation Review,* 14, 315–323.*

Using the telephone to follow-up mail attempts to secure parental permission, the researchers were able to reach a parent for 96 percent of nearly 3,000 students recruited for a "Healthy for Life" evaluation involving 6th graders. They concluded "The use of active verbal consent meets the demands for informed consent, while reducing the bias and cost burden that result when only active written consent is required." (p. 322).

If the study relied solely on the return of consent cards without telephone follow-up, the consent rate would have been only 58.6 percent (which was the return rate before telephone contact was made). If the study insisted on a returned card in addition to the telephone contact, the consent rate would have increased only an additional 8.5 percent (67.1 percent). By accepting the telephone consent without written documentation from the parent, the consent rate increased 20.4 percentage points, a very significant increase

Reference: Severson, HH, & Ary, DV (1984). Sampling bias due to consent procedures with adolescents. *Addictive Behaviors,* 8, 433–437.

Measuring drug use among 7th graders, these investigators concluded "The bias shown on significant dependent variables may adversely affect the generalizability of results of studies of adolescent drug use that depend upon positive parental consent." 604 7th graders were compared. Parents of 59.3 percent provided signed consent. Based on another survey, the researchers determined that the students without consent were significantly more likely to have been tobacco smokers, to have drunk alcohol, and to have smoked marijuana.

Reference: Severson, HH, & Biglan, A (1989). Rationale for the use of passive consent in smoking prevention research: politics, policy, and pragmatics. *Preventive Medicine,* 18:267–279.

RAND estimated that it cost (in 1987 dollars) $15/student (n=6,500) for active consent; a similar sized sample in an Oregon study cost about $1 per student, with passive consent. A University of Southern California research group estimated the cost to obtain written consent at $7.50/student for 8,000 students (in 1985 dollars). (The cost in the USC study may have been lower because a financial incentive was part of the procedure and because the students carried consent forms home, reducing postage costs.)

Reference: Thompson, T (1984). A comparison of methods of increasing parental consent rates in social research. *Public Opinion Quarterly,* 48, 779–787.

Several procedures were employed to increase parental consent rates in this study. One technique attempted to provide communication to parents by scheduling evening meetings to provide information about the study, but "when only one parent attended the first meeting and none the second, the meetings were discontinued." (p. 786) This suggests that it cannot be assumed that parents will be willing to make extra efforts to obtain information.

Senator STEVENS. Ms. Rusche, I am sorry. We will have to take your statement for the record. I hope you will accept my apology. I have no alternative but to go.

[The prepared statement of Ms. Rusche follows:]

PREPARED STATEMENT OF SUE RUSCHE

THE IMPACT OF THE FAMILY PRIVACY PROTECTION ACT ON THE ABILITY OF PARENTS TO PREVENT DRUG ABUSE IN THEIR FAMILIES AND COMMUNITIES

Thank you for the opportunity to testify here today about the impact of the Family Privacy Protection Act. I come before you as executive director of National Families in Action, the parent drug prevention organization I helped found in Atlanta 18 years ago. I also serve as president of the National Drug Prevention League, a coalition of national drug abuse prevention organizations that for the most part represent many thousands of community-based organizations. The League combines the strength of its member organizations to advance prevention and thereby reduce drug abuse. The Family Privacy Protection Act raises grave concerns among all of us who believe passionately in prevention and who support, advocate for and implement the careful evaluation of our work to ensure that we are achieving the results we seek. The Family Privacy Protection Act as written will virtually end our ability to collect reliable data about our own work. And it will end the ability of researchers who conduct national surveys to collect the data we rely on to mobilize parents and other citizens to take action to prevent drug abuse.

Over the years, National Families in Action has helped literally millions of parents prevent drug abuse in their families and communities. Our organization was founded in response to the escalation of drug use, abuse and addiction among adolescents and young adults that occurred in the 1960's and 1970's. The U.S. National Institute on Drug Abuse estimates that in 1962, only two percent of the population of the United States had had any experience with any illicit drug. By 1979, drug use among young people had escalated to pandemic proportions as the following chart illustrates:

Illicit Drug Use, 1960 to 1979	High School Seniors	Young Adults (ages 18–25)
Ever used	From 2% to 65%	From 2% to 70%
Used in past month	39%	37%
Used marijuana daily	11%	NA

Three factors appeared to drive this devastating escalation in drug use among the Nation's young people. First, eleven states decriminalized marijuana between 1972 and 1978, and the political rhetoric that accompanied this effort minimized or denied the harmful effects of the drug. Second, some 30,000 "head shops" emerged in the 70s, selling drug paraphernalia to entice youngsters into the drug culture. Third, the prevailing message in most drug education materials advocated teaching young people to use illicit drugs "responsibly," rather than not to use them at all, in compliance with the law. ("Responsible use" messages targeted to young people were extended to alcohol and tobacco, which are illegal for young people to purchase or possess.)

Founded in 1977, National Families in Action helped lead a national parent movement that worked to reverse these factors. In January 1978, the organization got through the Georgia Legislature the Nation's first laws banning the sale of drug paraphernalia. It helped others obtain similar legislation in their local communities or states, and taught them how to use this process to organize parent drug prevention groups. Next, the organization helped stop the decriminalization movement. No State has decriminalized marijuana since 1978, and several decrim States have increased their penalties at the behest of local parent groups. A Federal effort to decriminalize marijuana nationwide was also stopped. Finally, National Families in Action insisted upon reversing "responsible use" messages to "no use" messages in compliance both with the law and with medical and scientific-research indicating that drugs are harmful. We were joined in these efforts by our sister organizations, the National Parents Resource Institute for Drug Education (PRIDE) which was founded in Atlanta in 1978, and the National Federation of Parents for Drug-Free Youth (now the National Family Partnership), which both PRIDE and National Families in Action helped found in 1980.

As the parent movement grew and was joined by others throughout the 80s (such as the entertainment industry, media, business, government, community coalitions, the faith community and others), startling results were achieved, as the following demonstrates:

1. Between 1979 and 1992, regular (past month) use of illicit drugs was cut by more than half among Americans of all ages, from 24 million to 11 million.

Illicit Drug Use	1979	1992
Americans Who Used Drugs in Past Month	24 Million	11 Million

2. Even more remarkable, regular (past month) use was cut by nearly two thirds among high school seniors, from 39 percent to 14 percent, and young adults, from 37 percent to 13 percent.

Past Month Illicit Drug Use	1979	1992
High School Seniors	39%	14%
Young Adults (ages 18–25)	37%	13%

3. Most remarkable of all, daily marijuana use was cut by four-fifths, from 11 percent to 2 percent.

Daily Marijuana Use	1979	1992
High School Seniors	11%	2%

Sadly, as we know from the very surveys whose existence is now threatened by this legislation, drug use leveled off and reversed in 1991. After so much progress over 14 years, drug use among young people has once again begun to rise. As much as it breaks our hearts to have to do so, National Families in Action, the National Family Partnership and PRIDE are preparing to initiate a second effort to mobilize parents to stop this trend.

Mr. Chairman, if the Family Privacy Protection Act is passed, our efforts will fail. We will not be able to sound the alarm. We will not be able to mobilize parents without the single, most effective tool we have at our disposal: an accurate measure of what is happening to our children. I know that good intentions motivated the creation of the Family Privacy Protection Act. However, unintended consequences of the Act, as it is presently written, will destroy our ability to obtain the data we need to show parents, and the Nation, that something is wrong and we must take action to make it right. If we don't know, we can't act.

Statistics that charted the horrifying rise in drug use in the 70s provided the fundamental impetus for parents to act. Parents were outraged by drug paraphernalia, alarmed by decriminalization, and dumbfounded by "responsible use" messages, but their response would have been "so what? That won't affect my child." We couldn't have motivated them if we hadn't been able to show them that these factors were affecting all children, and it was only going to get worse unless we banded together and took action to change it.

The phenomenon of denial and its relation to addiction and to alcoholism is now fairly well understood. Family members do not see (deny) the slow changes in behavior that accompany drug use and addiction, so they take no action to get the addict help. It inevitably takes a crisis for the family to crash through its denial, recognize the problem and get the addict help—if the crisis was not fatal and there is still time to do so.

The Nation as a whole is subject to the same problem of denial. Without facts to make us see, we don't have to look. We can ignore the problem, pretend it isn't there, and use our time for other things, while the problem grows like a cancer and eats away at our very core—our children. For the 18 years National Families in Action has been helping prevent drug abuse, we have been able to confront denial because we have been able to show parents statistics about how many children are using drugs, and we have been able to use that information to motivate parents to take action. The Family Privacy Protection Act will throw us back into national denial at the very time parents must be mobilized as drug use once again begins to rise among young people.

A second point must be emphasized. At the strong urging of prevention advocates, Congress created the Center for Substance Abuse Prevention in 1986, established prevention demonstration grants and mandated that these grants contain rigorous evaluation components. As Principal Investigator of two CSAP grants, I can attest to the need to collect data about drug use (or, we hope, lack of drug use) among the children we serve, in order to fulfill the evaluation requirement Congress wisely mandated. We must first survey children in both our control and experimental groups before we begin our prevention work with the experimental group. We survey again when our work is completed and then conduct follow-up surveys for two years afterwards to determine whether the work we have done has prevented children from becoming involved with drugs. If the Family Privacy Protection Act is passed as written, grantees will no longer be able to collect this data because it will not be possible to obtain accurate response rates, given parents' tendency not to answer mail from the school. I know that this is not the intent of Congress.

I also know that Congress does not mean to block the ability of parents like Alaskans for Drug-Free Youth to fight against drug legalization initiatives. Until parents took action, the rate of marijuana use among young people in Alaska, where it was legal to possess up to four ounces of marijuana and to grow enough for "personal use," was several times higher than that of their counterparts in the other 49 states. This information, again derived from surveys this legislation threatens, was the driving force behind Alaskan parents' determination to overturn Alaska's decriminalization laws.

And I'm certain that Congress does not mean to make it virtually impossible for parents concerned about other self-destructive behaviors, such as eating disorders, teen pregnancy, suicide, and homicide, to obtain accurate data to guide them in their mobilization and prevention efforts either.

Finally, I know that Congress does not mean to tie the hands of the thousands of local parent groups and community coalitions who have done such an outstanding job of reducing drug abuse in the United States over the past two decades. Nor does Congress mean to make it impossible for us to redouble our efforts now that drug use is once again on the rise, not among adults, but among our children. Therefore,

I urge you, in behalf of the millions of American parents, families and communities that are trying to prevent drug abuse in the United States, to help us by amending this bill. We support informed consent with the opportunity to decline. We cannot do the work you want us to do with written parental consent.

Thank you for considering this request. I am appending to my testimony, and ask that they be inserted in the record, letters from Andrew W. Milwid, Jr., executive director, Elks Drug Awareness Program; Thomas J. Gleaton, Ed.D., president of PRIDE; and Reed Bell, M.D., Medical Issues Advisor to Focus on the Family and Dr. James Dobson.

Attachments follow:

LETTER FROM THOMAS J. GLEATON, ED.D., PRESIDENT, PRIDE

November 7, 1995

Sen. Ted Stevens, *Chairman*
Senate Governmental Affairs Committee
340 Dirksen Building
Washington, D.C. 20510

DEAR SENATOR STEVENS: The National Parents' Resource Institute for Drug Education (PRIDE) was founded to assist parents in preventing drug use by their children. Today, 847 communities in America have adopted PRIDE Parent Training. There are 11,603 PRIDE parent volunteer trainers across the Nation. They have given 6 million hours of training to 750,000 other parents. In addition, 407 communities have implemented the PRIDE Youth Program.

These efforts will be adversely affected if the Family Privacy Protection Act of 1995 (H.R. 1271) becomes law. The bill would require active consent of parents before drug survey responses could be sought from students. Even if the survey is completely anonymous and voluntary, signed and written consent of the parent would be necessary.

If this legislation is signed into law without significant change, parents in America could loose one of the most important public health indicators: the reporting of the local and national dimension of the adolescent drug use problem. Ironically, this action would come at the same time that PRIDE is reporting that two-thirds of parents are not communicating often with the children about drugs.

In 13 years of the PRIDE Survey we have received few complaints from parents even though more than 7 million students have responded to the survey. One group which has objected loudly to the PRIDE Survey is the drug legalization lobby. In the April 20, 1990, edition of the Atlanta Constitution, a spokesman for the Drug Policy Foundation claimed that PRIDE uses its survey to "drum up a lot of hysteria against marijuana and other drugs. Drug Policy is a Washington-based pro-legalization group.

The PRIDE Survey is administered anonymously and is voluntary. Students are not compelled to complete the survey instrument. Notice is often given through school board meetings, announcements in the press, and notices sent home to parents. Copies of the instrument are made available to the public for inspection. Many school systems report their data to the public by means of press releases and press conferences.

Requiring parental consent would:

- add greatly to the cost of administration of the survey
- place an undue burden on the school staff
- possibly contaminate research findings
- likely kill local efforts to assess drug problems and evaluate programs
- represent an unfunded Federal mandate to local education agencies

The greatest negative impact of the parental consent act could be felt by local organizations at a time when responsibility for solving the drug problem is being shifted to the states. Federally-funded research projects could possibly afford the added costs of parental consent But users of the PRIDE Survey are typically small school systems and community-based organizations. They pay only 86 cents per student to conduct a PRIDE Survey. That cost would rise 64 cents in postage alone if a First Class notice and stamped return envelope is required. Add the cost of handling and re-contact for non-responses, and the cost would more than double. In addition, the administration time would also more than double—effectively killing the ability of local programs to conduct the survey.

PRIDE believes the threats that are posed by the Family Privacy Protection Act were unforeseen and unintended by the Congress, especially Members who won elec-

tion last November on the appealing message that local problems are best solved by local solutions.

Last week alone, PRIDE saw Senators Grassley, Dole and Hatch use the PRIDE survey data to warn the Nation of rising adolescent drug use. This service of PRIDE would be lost if the Family Privacy Protection Act becomes law as written.

We urge you to exempt drug surveys, like the PRIDE Survey, from the application of this act.

I am attaching a letter from Dr. Reed Bell, medical advisor to Dr. James Dobson and Focus on the Family, in which he states his concern about this legislation. I wish that my letter and Dr. Bell's be included in the written testimony of the Committee.

Sincerely yours,

THOMAS J. GLEATON, ED.D.
President

LETTER FROM REED BELL, M.D.

97 SHORELINE DRIVE,
GULF BREEZE, FL 32561

November 6, 1995

SENATOR CHARLES GRASSLEY: I am writing as a Pediatrician who has been active long-term in seeking to prevent substance abuse in our youth. Also, I have served as a Medical Issues Advisor to Focus on the Family and Dr. Dobson. As you know, we (Focus) have rigorously supported your Parental Rights and Responsibility effort that would restore the clear authority of parents to direct the education of their children.

H.R. 1271—"The Family Protection Act of 1995" seeks to assure Family Privacy Protection in activities or programs funded by the Federal Government. However, I would appeal to you to provide language that would make an exception to the voluntary anonymous survey conducted by the Parents Resource Institute for Drug Education (PRIDE) a private parents' directed organization. They could provide "advance public availability" of their survey but would be severely hampered and cost-ridden if written parental consent is required. PRIDE's Survey is a "low-risk" inquiry that should not require parental or guardian signature.

This particular survey along with NIDA's survey are the only two (2) that can provide the critically necessary information to adequately and appropriately monitor substance abuse in our youth. This information is crucial to efficient and effective direction of substance abuse prevention efforts.

Senator Grassley, we are thankful and proud of your efforts to restore parental authority. We thank you for your kind consideration of this exception in order to keep parents informed of drug use in their communities.

Sincerely,

REED BELL, M.D.

LETTER FROM ELKS DRUG AWARENESS PROGRAM

GRAND LODGE ORDER OF ELKS,
JACKSON'S GAP, ALABAMA
November 7, 1995

Senator Ted Stevens
Alaska R

DEAR SENATOR STEVENS, It has been brought to our (my) attention that the language in H.R. 1271, "Family Protection Act of 1995" will prevent or seriously damage the collection of data from students on their use of drugs and related behaviors. The collection of data by most national and local groups do not require students to participate, and the student remains anonymous.

If parents must sign for each student to participate the collection of data would double in cost and schools will be very unlikely to conduct the survey. It will become almost impossible to keep parents informed of increases or decreases in drug use in their schools and communities. When surveys are conducted in local schools and the sample is of the total student population the old "not my kid" denial is often taken away. The explicit consent requirement will take away the best tool we have for measuring if a commodity is being successful or unsuccessful in their drug prevention programs for youth.

The results of these surveys are used:

(1) To help the Elks National Drug Awareness Program and their 1.5 million members stay informed about the level of drug use among America's youth and to give this information to others in their communities.

(2) To help parents monitor drug use in their child's age group and in their child's school. (Parents are not often impressed by national samples.)

(3) To help DEA quantify, at an early stage, the emergence of use among students of illegal drugs. (The increase in LSD in 1989 is an example.)

(4) To provide a partial basis for the Center for Substance Abuse Prevention's Urban Minority Youth initiative.

(5) To alert the news media to the overall increase in illicit drug use among adolescents. (The local media is most interested in local data.)

(6) To establish the relationship between alcohol and drug use and violent behaviors.

(7) To provide base line data for the U.S. Department of Justice Source Book of Criminal Justice Statistics.

(8) To assist the Center of Substance Abuse Prevention in understanding the current rise in marijuana use.

(9) To help Congress understand what works in prevention by providing evaluation base line data.

There is a growing lobby for the legislation of drugs, especially marijuana, across our Nation. A valid reason for not legalizing drugs is their use by our youth. If we are not persistent in pointing out the use and related violent behavior we are likely to see the current situation, which is bad, grow even worse.

The present wording of H.R. 1271 will support those who encourage legalization and obstruct local schools and communities in their effort to keep parents informed of drug use in their communities.

We hope you will correct the language and declare those surveys, local or national, which provide for "non-required" and "anonymous" status of students to be considered "low risk inquiries" and not be subject to a parent or guardians signature.

The above language or similar language will provide for protection of "family privacy" and the "need for families" to be informed about drug use and violence in their neighborhood, school and the larger community.

The matter is serious and your attention is appreciated.

Sincerely,

ANDY MILWID,
Executive Director,
Elks Drug Awareness Program

Senator STEVENS. Thank you very much. We might have some questions to follow up for the record, and we will send them to you.

Thank you very much.

[Whereupon, at 10:39 a.m., the Committee was adjourned.]

APPENDIX

IIA

104TH CONGRESS
1ST SESSION

H. R. 1271

IN THE SENATE OF THE UNITED STATES

APRIL 5, 1995

Received; read twice and referred to the Committee on Governmental Affairs

AN ACT

To provide protection for family privacy.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Family Privacy Protection Act of 1995".

20-957 97 - 3

SEC. 2. FAMILY PRIVACY PROTECTION.

(a) RESTRICTION ON SEEKING INFORMATION FROM MINORS.—Notwithstanding any other provision of law and subject to section 6, in conducting a program or activity funded in whole or in part by the Federal Government a person may not, without the prior written consent of at least one parent or guardian of a minor or, in the case of an emancipated minor, the prior consent of the minor, require or otherwise seek the response of the minor to a survey or questionnaire which is intended to elicit, or has the effect of eliciting, information concerning any of the following:

(1) Parental political affiliations or beliefs.

(2) Mental or psychological problems.

(3) Sexual behavior or attitudes.

(4) Illegal, antisocial, or self-incriminating behavior.

(5) Appraisals of other individuals with whom the minor has a familial relationship.

(6) Relationships that are legally recognized as privileged, including those with lawyers, physicians, and members of the clergy.

(7) Religious affiliations or beliefs.

(b) GENERAL EXCEPTIONS.—Subsection (a) shall not apply to any of the following:

(1) The seeking of information for the purpose of a criminal investigation or adjudication.

(2) Any inquiry made pursuant to a good faith concern for the health, safety, or welfare of an individual minor.

(3) Administration of the immigration, internal revenue, or customs laws of the United States.

(4) The seeking of any information required by law to determine eligibility for participation in a program or for receiving financial assistance.

(c) ACADEMIC PERFORMANCE TESTS.—Subsection (a) shall not apply to tests intended to measure academic performance except to the extent that questions in such tests would require a minor to reveal information listed in a paragraph of subsection (a).

SEC. 3. NOTIFICATION PROCEDURES.

The head of any Federal department or agency which provides funds for any program or activity involving the seeking of any response from a minor to any survey or questionnaire shall establish procedures by which the department, agency, or its grantees shall notify minors and their parents of protections provided under this Act. The procedures shall also provide for advance public availability of each questionnaire or survey to which a response from a minor is sought.

SEC. 4. COMPLIANCE.

The head of each Federal department or agency shall establish such procedures as are necessary to ensure compliance with this Act and the privacy of information obtained pursuant to this Act by the department or agency and its grantees. Nothing in this Act shall be construed to foreclose any individual from obtaining judicial relief.

SEC. 5. MINOR DEFINED.

In this Act, the terms "minor" and "emancipated minor" will be defined under the laws of the State in which the individual resides.

SEC. 6. APPLICATION.

This Act does not apply to any program or activity which is subject to the General Education Provisions Act (20 U.S.C. 1221 et seq.).

SEC. 7. EFFECTIVE DATE.

This Act shall take effect 90 days after the date of the enactment of this Act.

Passed the House of Representatives April 4, 1995.

Attest: ROBIN H. CARLE,

Clerk.

PREPARED STATEMENT OF SENATOR GLENN

These days our families and communities are confronted by many pressing issues that affect the health and welfare of our children—juvenile crime, drug abuse, teen pregnancies—to name just a few. To address these issues, law enforcement, health professionals, researchers, and government agencies need to get reliable information on the facts of our childrens' lives.

The legislation we consider today is based on the idea that family values are somehow compromised by research into children health and welfare issues. I understand the concern (we always need to respect and support the integrity of the family), but I believe the fear is misplaced.

Researchers are already governed by rules on parental notification, consent, and confidentiality. And the Paperwork Reduction Act ensures that the Office of Management and Budget reviews surveys for their necessity and practical utility. If there are problems with any of these procedures, we should address them. We should not go farther and undermine important research that is needed to help fight pressing social problems.

I think we need balance here. Ignorance is not an effective approach to identifying and solving social problems. I understand the sensitivities behind the legislation, but I am very concerned that the legislation will do more harm than good.

I hope today's witnesses will shed light on this issue and will help the Committee find the right approach in its deliberations on this legislation.

I ask consent that a number of letters I have received, as well as a written statement from the Department of Health and Human Services, be added to the record of this hearing.

Attached letters follow:

Letter from NERI Research Institutes

Senator John Glenn
Senate Governmental Affairs Committee
326 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Glenn: We are writing to unequivocally state our emphatic opposition to the Family Privacy Protection Act (H.R. 1271) which was recently passed by the House and now is before the Committee on Governmental Affairs. This legislation will severely impinge on scientific research currently being conducted as well as all future research with minors.

The bill includes provisions which would require written parental consent for any minors who are asked selected questions as part of any program or activity funded in whole or part by the Federal Government.

As a research scientist with over twenty years of experience and as a Director of a public health research firm with over twenty federally funded projects, I believe this legislation is both unnecessary and unduly onerous to those of us in the field attempting to collect scientifically impeccable data for public policy and direct service purposes.

Moreover, it will most likely result in lower response rates for all research efforts involving children and adolescents and concomitantly will compromise the validity and quality of our country's scientific research. It is already extremely difficult to obtain adequately high levels of response rates in such research because of the capricious nature of minor subjects and the inherent difficulties in reaching at-risk populations. To add another restriction would simply decimate any further research work within these age groups.

Of particular concern is the bill's specific singling out of research surveys which ask questions related to: (a) mental or psychological problems; and (b) sexual behavior or attitudes. This legislation, in effect, states that if, for example, we were to conduct surveys related to suicidal tendencies or sexual risk behaviors among children and adolescents (both of which are priority areas under the Healthy People 2000 Goals and Objectives) we would be required to obtain written parental consent. However, if our surveys were to address the incidence of family violence (certainly an area requiring as much confidentiality and adept management as either of the other two areas of concern), we could proceed without written consent.

Finally, there are currently enough protocol options for researchers to choose from to insure parental consent when minors are involved. Furthermore, as required by all Federal agencies, every one of our projects has received a rigorous scrutiny and review by an Institutional Review Board which is charged with the protection of all human subjects, including and most particularly, children and adolescents.

In sum, the proposed legislation is unnecessary, unduly burdensome, and discriminatory in approach. We urge you to defeat this legislation on every level.

Sincerely,

JOHN B. MCKINLAY, PH.D.
Vice President and Director

LETTER FROM TRI-ETHNIC CENTER FOR PREVENTION RESEARCH

September 19, 1995

The Hon. Senator John Glenn
Ranking Minority Member,
Senate Committee on Governmental Affairs
503 Hart Senate Office Building
United States Senate
Washington, D.C. 20510

Re: H.R. 1271, The Family Privacy Protection Act of 1995

DEAR SENATOR GLENN: This bill is likely to come before the Senate Governmental Affairs Committee for consideration in the next month or so, and then to the full Senate. I urge you to either oppose or amend it.

H.R. 1271 will create an inflexible requirement that surveys or other inquiries involving minors must have the written consent of parents in advance. I am very concerned about the serious unintended impacts of this inflexible requirement on research dealing with some of the country's most important problems including drug use and delinquency. I am seriously concerned about the impact it will have on accurate reporting of data related to special population such as American Indians. This could lead to severe underreporting of the extent of these negative influences and result in programs and interventions that may be inappropriate to the real issues.

The difficulty comes from the fact that a large portion (often more than half of all parents) do not answer when their written permission is sought, yielding overall survey response rates so low as to render the surveys worthless. This generally does not reflect their disapproval of the survey, since telephone follow-ups have shown that often only 1 percent to 2 percent of all parents actually object to their children participating in established surveys. Many parents simply do not answer such mail.

Alternative methods exist which meet the objectives of the bill—i.e. notifying and informing parents in advance, and giving them a chance to decline—but without all the unintended consequences.

This bill does not serve the interests of the parents and it certainly does not serve the interests of the country. Finally, it puts special populations at a severe disadvantage with few resources to collect accurate data and fewer opportunities for funding appropriate interventions.

Yours sincerely,

ERNEST CHAVEZ, PH.D.
Professor

LETTER FROM SRI INTERNATIONAL

November 7, 1995

The Hon. John Glenn (OH)
c/o David Plocher
United States Senate
Washington, DC 20510

DEAR SENATOR GLENN: As director of SRI's Education and Health Research Division, I am writing to draw your attention to a troubling provision of the Family Privacy Protection Act of 1995 (H.R. 1271).

By requiring that absolute written consent be obtained from parents before minors can participate in any federally funded survey, the legislation would jeopardize research intended to give policy makers the information they need to make appropriate decisions.

It is well-established that many parents do not return written consent forms, not because they object to the proposed activities, but simply because the forms are lost or forgotten. Unfortunately, this problem is large enough that those minors whose parents do return forms in a timely fashion are not a representative sample of all

youth. To obtain scientifically valid samples, researchers world have to institute laborious processes for obtaining permission over a period of weeks with repeated reminders sent home to parents. The result would be an increase in research costs, more burden on the family, and/or samples that are too small or lack representation of key groups.

Both ethical standards and research practice already provide for a minor's right to refuse to participate. Moreover, all federally funded research is already subject to scrutiny for the protection of human subjects by Institutional Review Boards and to review by the Office of Management and Budget (OMB). Flexibility is needed in working with local education agencies to determine the most appropriate way to communicate with their local population of parents (e.g., from homes where English is not spoken)

We support the goal of protecting family privacy and the confidentiality of participant data, but believe that instead of advancing this goal, H.R 1271 would undermine researchers' ability to obtain the data that can provide an empirical basis for decision making.

Sincerely,

BARBARA MEANS
Executive Director
Education and Health Division

PREPARED STATEMENT OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Subcommittee: Thank you for the opportunity to share with you the concerns of several agencies within the Department of Health and Human Services (HHS) regarding H.R. 1271, the "Family Privacy Protection Act of 1995." Included in this statement are the responses of the Administration for Children and Families (ACF) and several agencies of the Public Health Service (PHS) to questions posed by the House Government Reform and Oversight Subcommittee on Government Management, Information, and Technology during the Subcommittee's consideration of the bill.

Before we turn to the responses of individual HHS agencies, we would like to summarize our concerns about the bill's requirement for prior written parental consent, as currently drafted. While we strongly agree that parental involvement and consent are essential in studies that include minors, the Department believes that changes should be made to the procedure in the bill for documentation of this consent. The requirement for prior written consent could seriously jeopardize the ability of these studies to provide Federal, State and local policy makers with useful, quality information. Further, in programs such as those serving runaway youths, the requirement for written consent, prior or otherwise, may be logistically impossible or even may be incompatible with the best interests of the children receiving services.

In carrying out research involving human subjects PHS follows the requirements set forth in the Federal Regulations for the Protection of Human Subjects (45 CFR 46). In addition, study protocols must be approved by the institutional review boards (IRBs) of the research entities and the peer review processes of the agencies, as well as the schools when studies are school-based.

A prior written consent procedure is likely to undermine the validity of study conclusions by negatively affecting participation rates and introducing response bias. Requiring prior written consent will harm the quality of the data because of a likely increase in nonresponse rates. Further, study findings may be significantly biased. There is evidence that parents who return survey consent forms are somewhat different, as a group, from those who do not respond. It is likely that just those children we wish to help, children at high risk, will be those whose parents will lack the motivation to respond.

An alternative would be to provide for parental notification and to afford parents or guardians the opportunity to respond orally or in writing that they do not wish their child to participate in the study. The current procedure of allowing the child to refuse, even if the parent has not refused, should continue.

Agency—Specific Responses:

ADMINISTRATION FOR CHILDREN AND FAMILIES

1. What surveys, analyses, or evaluations of individual minors are currently conducted with Federal funds?

Answer: Program evaluations and other such studies, evaluations of family and youth programs, such as the Runaway and Homeless Youth Act and the Transitional Living Program for Homeless Youth, supported at the Federal, State or local levels routinely ask questions of youth related to the reasons they sought services from the programs and whether these problems have improved as a result of the services received which may relate to "mental or psychological problems potentially embarrassing to the minor or his family . . ." as a means of determining the effectiveness of the services provided. Similarly, questions related to issues such as sexual behavior may be asked as vehicles for measuring changes in youth's functioning as a result of participation in these programs

2. What are the current policies and procedures for parental consent with these surveys, analyses or evaluations?

Answer: Participation of youth (and of their parents or guardians, as applicable) is totally voluntary in evaluations of family and youth programs, such as the Runaway and Homeless Youth Act and the Transitional Living Program for Homeless Youth. These programs routinely ask questions of youth related to the reasons they sought services from the programs and whether these problems have improved as a result of the services received. Similarly, questions related to issues such as sexual behavior may be asked as vehicles for measuring changes in youth's functioning as a result of participation in these programs. The data are maintained and reported in such a way that the privacy and confidentiality of the information provided is ensured.

3. Are there circumstances under which parental consent, as required in the legislation would, in your opinion, not be appropriate?

Answer: Abuse and neglect and other "potentially embarrassing" family problems often constitute the reasons that youth run away from home. Obtaining information about these problems is critical in order for service providers to address these problems and to facilitate a youth's return home or placement in an alternative living arrangement.

Since many of the youth served by family and youth programs, such as the Runaway and Homeless Youth Act and the Transitional Living Program for Homeless Youth, have not yet reached the age of emancipation, and because it would be very difficult to obtain tide consent of parents or guardians prior to interviewing homeless youth or runaway youth who do not return home, these provisions would preclude the conduct of evaluations of these types of programs.

4. What are the impacts that you foresee as a consequence of this legislation?

Answer: As mentioned above, program evaluations and other such studies, evaluations of family and youth programs, such as the Runaway and Homeless Youth Act and the Transitional Living Program for Homeless Youth, would be impeded. These programs routinely ask questions of youth related to the reasons they sought services from the programs and whether these problems have improved as a result of the services received which may relate to "mental or psychological problems potentially embarrassing to the minor or his family . . ." as a means of determining the effectiveness of the services provided.

Similarly, questions related to issues such as sexual behavior may be asked as vehicles for measuring changes in youth's functioning as a result of participation in these programs. The participation of youth (and of their parents or guardians, as applicable) is totally voluntary and the data are maintained and reported in such a way that the privacy and confidentiality of the information provided is ensured. Since many of the youth served by these programs have not yet reached the age of emancipation, and because it would be very difficult to obtain the consent of parents or guardians prior to interviewing homeless youth or runaway youth who do not return home, these provisions would preclude the conduct of evaluations of these types of programs.

5. Do you have any suggestions for improvements to the legislation?

Answer: To avoid the problems discussed above, youth service programs should be exempt from these provisions.

CENTERS FOR DISEASE CONTROL AND PREVENTION

1. What surveys, analyses, or evaluations of individual minors are currently conducted with Federal funds?

Answer: CDC supports several school-based (The Youth Risk Behavior Study) and home-based (National Survey of Family Growth) surveys that determine knowledge, attitudes, behaviors and practices of adolescents concerning various health factors. Public health professionals use these data to determine new patterns of adolescent risk taking behavior and to develop more effective policies and programs to prevent risky behaviors.

All CDC sponsored surveys involving minors are voluntary. Most of our surveys do not collect personal identifying information. However, when personal identifiers are collected, they are only used to contact respondents at future times for follow-up assessment. Some data collections involving the collection of personal identifying information have legal protection of identity through an assurance of confidentiality.

Although CDC data are collected on the individual level, survey results are published and used in the aggregate. Public health interventions are developed based on the needs of the population rather than the individual.

2. What are the current policies and procedures for parental consent with these surveys, analyses or evaluations?

Answer: All national based surveys routinely obtain informed consent from parents of minor children. In most cases, the technique used is to read or show to the parent/guardian a form which explains the content of the survey, its authorizing legislation, and the confidential and voluntary nature of participation. The interviewer fills in the identifying information on the form and upon receiving the parent's permission, the interviewer signs or initials the document. The minor is then allowed to decide whether or not he/or she wants to participate in the survey.

Our school-based surveys are mostly implemented through the States. Therefore, these surveys comply with State laws concerning parental consent as well as protection of respondents in accordance with human subjects review boards.

3. Are there circumstances under which parental consent, as required in the legislation would, in your opinion, not be appropriate?

Answer: While CDC does support obtaining parental consent, it is often the case in survey research that obtaining written consent is logistically unfeasible. The process required to obtain written parental consent for school-based research often places unnecessary burden on school administrators and teachers, detracts from important instructional time, and may produce response that are so low as to threaten the quality and usefulness of the data.

Many surveys are conducted by telephone because that mode is much less expensive to use than in-person interviewing. Obtaining written consent for telephone interviews would be extremely difficult. Frequently the identity and address of the household is unknown prior to the initial call. Obtaining written consent from telephone respondents prior to conducting the interview would involve collecting additional personal identifiers in order to mail consent forms to the household. Valuable time and resources would be lost contacting and encouraging parents to return the signed forms.

As stated in the response to question 2, many of our national surveys involve obtaining verbal consent and documenting such consent. There has been no indication that the witnessed verbal consent technique has been either abused by interviewers or a cause of concern among minor respondents or their parents.

4. What are the impacts that you foresee as a consequence of this legislation?

Answer: If this bill were enacted, it would significantly decrease CDC's ability to generate data on adolescent health and risk behaviors, thus curtailing the effectiveness of prevention policies and programs for youth.

CDC uses its data to develop and target interventions to minors to prevent them from placing themselves at risk for various adverse health behaviors and effects. The collection of baseline data for risk reduction studies is fre-

quently performed. In this regard, this legislation would be extremely problematic as it would potentially restrict our ability to measure the effectiveness of risk reduction interventions because accurate baseline and intervention outcome data would not be obtainable.

The legislation could also greatly increase the cost of some surveys because in-person interviews would be required in order to obtain written consent. The legislation would preclude the collection of data for anonymous survey, which are often the best way to obtain information on high-risk behaviors, by forcing the survey subject to identify him or herself by name thus losing anonymity.

5. Do you have any suggestions for improvements to the legislation?

Answer: Delete the requirement for prior written consent. The approach to obtaining consent could then be designed asappropriate for each survey and would be included in the review conducted as part of the requirement to protect human subjects. One alternative to requiring written consent would be to obtain verbal informed consent over the telephone, or in person in the home, and allow the interviewer to document the consent.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Background:

SAMHSA is mandated to collect data on the incidence and prevalence of substance abuse and mental illness, characteristics of the alcohol, drug and mental health (ADM) treatment systems and the characteristics of individuals served, and other related information. In addition, SAMHSA must respond to Federal mandates to evaluate its major substance abuse treatment and prevention programs and mental health treatment programs, a number of which have minors as their primary focus. The collection of data on minors from statistical surveys and administrative records and the participation of minors in program evaluations are essential toSAMHSA's mission of providing national leadership in the areas of substance abuse and mental health services through knowledge development and dissemination.

In carrying out this mission, SAMHSA is acutely aware of the need to protect the privacy and confidentiality of the individuals served by SAMHSA funded programs or participating in SAMHSA's statistical data collections. Only the lowest level of identifying information is collected that will allow the study to achieve its analytic or programmatic objectives. For example, in the case of surveys of individuals in which respondents will not be followed up, data are collected anonymously. Similarly, in surveys of administrative records (record abstraction studies) information identifying individuals is not part of the abstracted record.

All regulations concerning confidentiality and privacy of patient records and protection of human subjects, i.e. 42 CFR Part 2 and 45 CFR Part 46, are followed. Where appropriate, SAMHSA funded contractors and grantees apply for Certificates of Confidentiality to further protect the data they collect. In studies where it is necessary to maintain a file of individual identifiers for followup or linkage purposes, the identifying information is kept in a secure place separated from other data about that individual. Identifiers are then destroyed as soon as the tracing or linkage purpose has been accomplished.

Response to Questions:

1. What surveys, analyses, or evaluations of individual minors are currently conducted with Federal funds?

Answer: These projects are listed below. Also listed are projects that collect data via abstraction of existing records. Because the end product of any survey or evaluation is data analysis, all of the projects shown below incorporate analytical activities.

All SAMHSA data collections in which *information is obtained directly from minors* require parental consent. Consent is obtained either actively or passively. Under active consent procedures, the parent, guardian, or responsible adult must specifically give the data collector permission for the child to participate in the study. In most cases, active consent is obtained in writing from the parent. (For one SAMHSA survey listed below, the NHSDA, active consent is obtained verbally rather than in writing.) Under passive consent procedures, parents are notified in writing that their children will be asked to participate in a study. If parents do not want their children to

participate they must return a form. If no form is returned, it is assumed that the parent has no objections to the child's participation in the study.

Whether parental consent is obtained actively or passively, the minor's participation is still voluntary. In no cases are minors required, coerced, or otherwise compelled to participate in the data collection.

- National Household Survey on Drug Abuse (NHSDA)—Anonymous interview survey of persons age 12 and over. Active, verbal consent of parent obtained. Written consent not obtained because survey is anonymous. Data is used for aggregate statistical analysis only.
- Drug Abuse Warning Network (DAWN)—A record abstraction survey of drug-related emergency room episodes and drug-related deaths as reported by selected medical examiners. Minor's records are abstracted, but abstraction is anonymous, i.e. individuals are not identified. Data is used for aggregate statistical analysis only.
- Drug and Alcohol Services Information System (DASIS)—The DASIS includes an anonymous record abstraction component, the Treatment Episode Data Set. States forward data on each admission to publicly funded substance abuse treatment units to SAMHSA. Records for minors admitted to treatment are included. Identifying information is not given to SAMHSA. Data is used for aggregate statistical analysis only.
- Evaluations of all grants for substance abuse treatment services funded by the Center for Substance Abuse Treatment (CSAT), require written parental consent for the participation of minors. These studies include: Evaluation of the Job Corps Drug Treatment Enrichment Program; Evaluation of the CSAT Adolescent Treatment Programs; and Evaluation of the Program for Pregnant and Postpartum Women and Infants.
- Evaluations of all grants for substance abuse prevention services funded by the Center for Substance Abuse Prevention (CSAP) include minors. Many of these evaluations require passive parental consent for the participation of minors. These include: Evaluation of the High-Risk Youth Program; and Evaluation of the Community Partnership Program. Passive consent means that the program sends forms to the parents explaining the study and asking parents to return a form only if they do not want their children to participate. If no form is returned, consent is inferred.
- Evaluation of the Comprehensive Mental Health Services Program for Children with Serious Emotional Disorders requires written parental consent.
- National sample surveys of substance abuse treatment outcomes that involve interviews with clients, such as the Services Research Outcomes Study; the National Treatment Study; and the Alcohol and Drug Services Survey require written parental consent before sampled minors are interviewed.

In addition, SAMHSA conducts several surveys of treatment facilities in which client data, including data on clients under the age of 18, are collected in aggregate form. These are not listed above.

2. What are the current policies and procedures for parental consent with these surveys, analyses or evaluations?

Answer: Procedures for parental consent for each SAMHSA survey and evaluation are shown above. Parental consent is obtained whenever *individuals are asked to provide information about themselves.* With the exception of the substance abuse prevention evaluation studies discussed below, all studies listed above require written consent of the parent or guardian for nonemancipated minors, and of emancipated minors for themselves. The evaluations of substance abuse prevention programs frequently rely on passive consent. Participation in all the SAMHSA studies is voluntary.

Parental consent is not obtained for the record abstraction component of treatment outcome studies such as those listed above. 42 CFR Part 2 permits disclosure of patient records for limited and specific purposes, including research and evaluation.

SAMHSA does not obtain parental consent in studies involving *anonymous record abstraction,* such as DAWN and DASIS. In this case, SAMHSA cannot identify individuals, therefore consent is irrelevant. Also, SAMHSA does not obtain parental consent to conduct "analyses" on databases that contain

data on minors. As described above, identifiers are not retained in the analytical databases.

3. Are there circumstances under which parental consent, as required in the legislation would, in your opinion, not be appropriate?

Answer: In the case of evaluation of substance abuse prevention programs, requiring prior written parental consent is likely to have a harmful effect on the minors' participation in prevention programs, and on the agency's ability to collect meaningful data on the effectiveness of the programs. Many of the high-risk youth participating in substance abuse prevention programs may have parents who are unlikely to provide written consent for their children's participation in prevention programs, or in evaluation of such programs. These may include parents who are substance abusers, or who abuse or neglect their children. Requiring written consent for participation in evaluations may prevent such children from participating in the prevention programs, themselves.

Furthermore, requiring written parental consent is likely to harm the quality of the data from such evaluations. If the evaluations only include data from children whose parents provide written consent, it is likely that children at higher risk will be under-represented in the studies. This means that study results will be considerably less accurate in measuring program effectiveness, and in providing information for future policy and program planning.

A requirement for parental consent, in any form, does not make sense in terms of anonymous record abstraction or analysis of aggregated data. In neither case is there any risk to the minor whose information is included in the aggregate data base.

4. What are the impacts that you foresee as a consequence of this legislation?

Answer: This legislation could unnecessarily impede the work of the Agency in carrying out its mandates related to knowledge development and dissemination. Congress would not have the data needed to assess the effectiveness of SAMHSA programs and other Federal efforts related to substance abuse and mental health.

SAMHSA endorses the concept of written parental consent in those causes where the risk of potential harm is present. But it is important for agencies to have some flexibility in determining the appropriateness of written consent, as contrasted to passive consent, procedures. In the case of the prevention studies, the harm done by being unable to assess the impact of prevention programs targeted at youth would outweigh the virtually nonexistent harm that would follow from a passive consent procedure.

The inability to conduct data analysis or administrative record abstraction studies—a conceivable consequence of the proposed legislation—would, of course, be extremely damaging and not in the interests of the government or the public.

5. Do you have any suggestions for improvements to the legislation?

Answer: We believe that an exception needs to be made for the abstraction of anonymous records and surveys that do not include identification of individuals. We believe that secondary analyses of data which are not intended to and cannot identify individuals should not be covered by this legislation because it would unnecessarily limit the use of data. For example, recently we prepared analyses of the risks to children from family drug abuse. These were designed to show how many children live in households where their parents use drugs.

National Institutes of Health (NIH)

The NIH institutes and centers support a variety of research studies that may involve surveys, analyses or evaluations of individual minors. These research studies include, but are not limited to, the following: surveys of children's oral health, studies of children who are considered at high risk for alcohol abuse; research to access school-based interventions which promote healthful behaviors in areas such as cardiovascular disease, obesity, and asthma; research which focuses on the extent and nature of drug use in adolescent populations; and research concerning pregnancy,

sexually transmitted diseases, and eating disorders affecting adolescents. Below, as examples, are how Title IV would affect two NIH institutes.

NIH/National Institute on Drug Abuse

1. What surveys, analyses, or evaluations of individual minors are currently conducted with Federal funds?

Answer: Data on drug using behaviors among adolescents and other minors provides an indication of a potential "epidemic" in drug use. For that reason, and to collect information to inform prevention activities, the National Institute on Drug Abuse (NIDA) sponsors a number of home- and school-based studies that collect data from minors on drug use and related factors. The most visible of these efforts is the Monitoring the Future (MTF) Study (also known as the High School Senior Survey), which is conducted annually by the University of Michigan under a NIDA grant. MTF is the government's primary means of tracking drug use among the Nation's youth.

Under its extramural program, NIDA also sponsors numerous additional studies that focus on young people in the effort to measure the extent and nature of drug use, to identify its causes, and to develop interventions to prevent or treat the problem. One of these other studies is an ongoing survey of American Indian and Alaskan Native youth, a group at high risk of developing substance abuse problems. These studies are an essential part of the Nation's efforts to measure, understand, and combat the drug problem among its youth.

Other examples of federally funded studies are: one, a study of 3rd-6th graders about their knowledge, beliefs, and attitudes about drug abuse and the relationship of drug abuse to AIDS (Wells, University of Washington); and two, identification of drug and HIV risk factors and assessment of the effectiveness of an intervention to decrease aggression and other anti-social behaviors among a sample of Baltimore City school children (Anthony, Johns Hopkins).

2. What are the current policies and procedures for parental consent with these surveys, analyses, or evaluations?

Answer: Parental consent is a part of the protocol for all NIDA-supported studies that collect data from minors, whether the minors are contacted in the home or the school. Procedures for obtaining and documenting consent vary from one study to another, but protocols for all studies of minors must provide for parental consent as well as addressing other human subjects issues. Protocols must be cleared thr6ugh Institutional Review Boards (IRBs), the NIH extramural review process, and internal NIH officials. The clearance process considers risks to the child; appropriateness of study content for children of the target ages; informed consent from both child and parent; and other issues.

With school-based surveys, the most common procedure for obtaining parental consent involves giving parents written notification of the survey, including its purpose and contents, and asking them to respond if they object to their child's participation. The notification is either mailed by the school to the parents directly, as in the. MTF study, or, more typically, sent home to the parent through the child. Parents can withdraw their children from participation in the study by calling the school or responding in writing. They are not required to justify their objections. Numerous studies using this procedure have been reviewed and approved by IRBs and NIH extramural committees and internal groups. Equally significantly, numerous studies using this parental consent procedure have been approved by school boards and administrators. Approval at the school level is essential, and investigators do everything they can to resolve problems. before they reach this stage. In addition to parental consent, minors surveyed in NIDA-sponsored studies also have the option of refusing participation and are so advised.

With home-based surveys of minors, parental consent is always required. Studies vary, however, in whether the parents' signatures are obtained.

3. Are there situations under which parental consent, as required in the legislation would, in your opinion, not be appropriate?

Answer: We believe the requirement for signed documentation of consent would be inappropriate in some situations. In school-based surveys, studies have found that large numbers of parents don't respond when a form is sent to them asking them to approve or disapprove participation. Follow up notifications have shown that the overwhelming majority of these non-responding parents approve of their child's participating in the survey, but just did not return the form. If parents are required to return a signed document, many children will be excluded from participation simply because the parents who approve their child's participation did not return the form. Home-based surveys have less of a problem dealing with the signed documentation of consent requirement than school-based surveys because interviewers in home surveys have direct contact with the parents.

4. What are the impacts that you foresee as a consequence of this legislation?

Answer: The requirement for signed documentation of parental consent under this legislation will have several adverse effects, particularly on school-based surveys. First, this procedure will create a vast amount of administrative work. More of this administrative work will fall on the schools rather than the researchers, because many schools have policies that restrict outside researchers' access to parents' addresses and phone numbers. This added administrative burden may result in refusal of large numbers of scho6ls to participate.

Second, because of parents not returning forms, the requirement for signed documentation of consent will greatly reduce the available samples of children for these studies. This will result in either reduced reliability and precision of study findings or in greater cost because of the need to increase sample sizes to offset attrition.

Third, and more seriously, study findings may be biased significantly by the nature of the children in the samples available under the new procedure. Regardless of whether parents approve or disapprove of their children's participation, parents who return survey consent documentation forms are somewhat different, as a group, from those who do not. This creates a bias in the sample of children. For example, in a 1983 study of procedural factors affecting an evaluation of an alcohol education curriculum, Kearney, Hopkins, Mauss, and Weisheit (Public Opinion Quarterly) reported that 34 percent of parents did not return the forms that were sent out. More white than African American or Asian-Pacific Islander parents sent in the forms. Seventy-eight percent of all parents consented to their children's participation, but this rate also was lower for racial/ethnic minorities than for whites. The overall effect of the signed documentation of consent procedure was a sample that overrepresented white students and underrepresented African American and Asian students.

Response rates in many cases may be lower than those achieved in this study. In study of drug use in which signed documentation of parental consent was sought for minors' participation in a survey at an inner city school, the University of Michigan (Johnston, personal communication, 1995) found that only 17 parents out of 100 returned the form, resulting in a 17 percent response rate.

Other factors not considered in this study may influence the likelihood of parents' returning survey consent forms and approving their children's participation, and these other factors may bias the survey sample and the findings. For example, NIDA is concerned that parents who use illicit drugs might be less likely to return a consent form. In 1991, 11.3 percent of parents who live with their children reported illicit drug use in the past year (DHHS, 1994). If situations of this type were common, the resulting bias in survey findings could not be corrected and would not even be known. This would seriously jeopardize the credibility of the survey results.

If written parental consent procedures reduce the feasibility and accuracy of school-based surveys and increases their cost, it may be necessary for more researchers to collect data on children using home-based surveys. This would greatly increase the cost of conducting the necessary research. It also might undermine the validity of self-reports of sensitive behaviors, as children are more reluctant to report such behaviors when surveyed in their homes with their parents present. Although special techniques are available

to ensure children's privacy in responding to surveys in the home, these procedures are expensive and may not work with young children.

5. Do you have any suggestions for improvements to the legislation?

Answer: We believe that the signed documentation of parental consent procedure required under H.R. 1271 overcompensates for the current problems and creates numerous additional problems that increase the cost and difficulty of conducting research on minors and reduce the validity of the findings of that research. An additional problem with the proposed legislation is that some of the survey consent forms sent home to parents through their children may not reach the parents; thus, these parents do not have the opportunity to review the issue.

To strengthen the current procedure while avoiding the potential problems associated with the signed documentation of parental consent procedure, we recommend that the legislation be revised to accept a different form of evidence of parental consent. Parental consent would still be required, and signed documentation of consent would still be acceptable. We propose, however, to accept for school-based surveys the following circumstances as documentation of parental consent:

(a) Parents have been notified in writing of the intended survey, its purposes and contents, through letters sent directly to them through first class mail. Sending forms home through the children would no longer be acceptable notification. While we feel that it will strengthen current procedures, there will be an increased burden on the schools which will more than likely be responsible for mailing and processing the letters.

(b) Parents who, for any reason, wish to withdraw their child from participation in the study could do so by (i) returning the form with a signature denying permission, (ii) calling the school indicating their desire to withdraw their child, or (iii) calling a toll-free number provided by the researcher (if different from the school district) to withdraw their child. Addressed, stamped return forms shall be provided to facilitate parents' responding.

(c) Notification would be required to be mailed to parents at least two weeks prior to the planned survey date, and parents may register their disapproval of their children's participation at any time prior the survey.

(d) Any child whose parent has been notified as described above and has not registered disapproval will be eligible to being surveyed. As in current procedures, children have the right to refuse regardless of the fact that their parents may not have disapproved of their involvement in the study.

This suggested procedure for documenting parental consent would balance the parents' rights and responsibilities with the need to continue to conduct research on vital issues of child health and well being. Although the suggested changes would require modification of the protocols for numerous planned and ongoing studies and would entail some increase in costs, these changes would avoid needless costs, difficulties, and introduction of bias while improving parents opportunity to review and control the information their children are asked to provide.

NIH/National Institute on Child Health and Human Development

1. What surveys, analyses, or evaluations of individual minors are currently conducted with Federal funds?

Answer: The National Institute of Child Health and Human Development (NICHD) supports a range of research, including surveys, analyses, and evaluations, that involve individual minors in both home and school settings. The major topics of that research are adolescent pregnancy, sexually transmitted diseases including AIDS, acquisition of productive skills and behaviors, parent-child relationships, intergenerational family dynamics, and adolescent eating disorders.

The adolescent pregnancy studies look at factors that contribute to unwanted pregnancy and its consequences, for example premarital childbearing, poverty and welfare policy, and the impact of mentoring and stress on pregnant adolescents. The studies concerned with sexually transmitted dis-

eases and AIDS include interventions to decrease risk and to prevent infection. The studies of productive skills and behaviors are used to monitor the transition from minor dependency to independent adult status. The studies of parent-child relationships are used to examine the role of families in the development of successful adults. The studies of intergenerational family dynamics are used to examine the causes of welfare dependency, out-of-wedlock childbearing, and the effect of family turbulence over the life course. Finally, the studies on adolescent eating behaviors include research on anorexia, bulimia, and obesity.

2. What are the current policies and procedures for parental consent with these surveys, analyses, or evaluations?

Answer: As with all NIH-funded research involving human subjects, the NICHD-supported studies described above meet the requirements of the Federal Regulations for the Protection of Human Subjects (45 CFR 46. These regulations require formal written consent by a subject or written permission of the subject's agent, such as a parent of a child (person who has not attained the legal age for consent, as defined by the law of the jurisdiction where the research is conducted), however, the requirement for written consent or permission may be waived if: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

3. Are there situations under which parental consent, as required in the legislation would, in your opinion, not be appropriate?

Answer: There are some circumstances where the written consent requirement in the legislation would create a significant burden, or even make it not feasible to conduct the research. The Federal Regulations for the Protection of Human Subjects, while generally requiring written consent, also recognize that such written consent is not always appropriate, and allow for other forms of consent as long as they afford both the subject and the subject's agent (parent or guardian) the right to be informed about the study before agreeing to participate,.as well as the authority to decline to be a subject of the research.

4. What are the impacts that you foresee as a consequence of this legislation?

Answer: Enactment of this legislation as proposed would impact negatively on the research of the NICHD in the following three ways:

- Reduce response rates—Field research has shown that while very few parents have any objection to their children participating in such research, many more will either not get around to sending in a signed written consent, or will not do so because they are put off by the legal nature of the document. For studies to produce results that are representative of the population being studied, it is essential that high participation rates be obtained.
- Increase costs—The extra effort necessary to obtain an adequate response of written consent from parents or guardians is very costly, whether conducted in the home or school. It is likely to require several more attempts to reach the parent and persuade them to send in the consent form. Because schools are prohibited, in most cases, from providing researchers with information about parents, this added workload is likely to fall most heavily on school personnel, and, perhaps, result in the school being unable to assume that added expense and declining to participate in the study.
- Increase the likelihood of bias in the study result—The extra burdens of requiring "written" informed consent are likely to affect disproportionately certain groups in the study population. Specifically, lower socioeconomic groups, families where English is not the primary language, families under stress, and various minority groups, are the most likely to not return written consent forms and, thereby, decrease, or even eliminate, the necessary inclusion of such groups.

5. Do you have any suggestions for improvements to the legislation?

Answer: If there is found to be a need for such legislation, we would suggest that the narrow requirement for "written" consent be replaced by a provi-

sion that is consistent with the provisions of the Federal Regulations for the Protection of Human Subjects (45 CFR 46), which, in 1991, were made the guidelines that are followed by most agencies of the Executive Branch of the Federal Government.

In addition, we would suggest that the consent of the minor, whether emancipated or not, as well as that of at least one of the minor's parents or guardians, be sought. As drafted, only an emancipated minor would have the right to object to participating in the research. The Federal Regulations for the Protection of Human Subjects would urge that the consent of the unemancipated minor be obtained as well.

LETTER FROM THE U.S. DEPARTMENT OF JUSTICE

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF LEGISLATIVE AFFAIRS
November 14, 1995

Hon. Ted Stevens, *Chairman*
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

DEAR MR. CHAIRMAN: The Department of Justice has reviewed H.R. 1271, the "Family Privacy Protection Act of 1995." We understand that this legislation was referred to the Committee on Governmental Affairs after having passed the House. As passed, H.R. 1271 will have a detrimental effect on Department of Justice programs. In addition, the bill will limit the Department's ability to provide quality, reliable information on issues ranging from the use and sale of drugs by juveniles to child victimization.

Under Section 2(a), the prior written consent of a parent or guardian is required prior to seeking certain categories of information from minors in any federally funded program or activity that surveys such information. The "prior written consent" provision would impede the collection of critical information by drastically reducing response rates, introducing bias in study samples, reducing the reliability of research, and dramatically increasing the cost of surveys. Studies have found that approximately half the parents do not return consent forms when written consent is requested. Further inquiries revealed that parents did so not out of concern but from inertia. When contacted directly, only 1 percent refused. Under current DOJ practice, participation is always voluntary and confidential and provides a means for a parent or guardian to disallow their child's participation.

Sec. 2(a) (4) and (5) extend coverage to "(I)llegal, anti-social, or self-incriminating behavior" and "(A)ppraisals of other individuals with whom the minor has a familial relationship." The result of these provisions is tiat valuable information regarding criminality, drug abuse, child abuse, and child abduction will no longer be available. Information on the use of guns, drugs, or prior criminal history records is most often solicited of arrestees. Common sense explains the nearly impossible task of collecting prior written consent from the parents of this population. In addition, a parent who is abusing a child is unlikely to sign a consent form allowing that child to participate in an interview or survey of this nature. The practical effect would be to impede the ability to obtain critical information about the Nation's most "at-risk" minors.

The Department of Justice, for instance, relies on studies such as the Drug Use Forecasting (DUF), which, like the University of Michigan's *Monitoring the Future* study, measures the prevalence of drug use by minors. The DUF surveys arrested minors about their drug use, providing a vital early warning system of drug use trends among juvenile offenders. The written consent provision in H.R. 1271 would effectively eliminate the DUF. A key indicator of drug use and enforcement effectiveness would be lost.

Policy makers rely on the DUF and other indicators such as the National Criminal Victimization Survey (NCVS), evaluations of boot camps, and surveys of gun use to decide what course is prudent and how to maximize impact with limited funds. Many issues from drug abuse to child abuse have been informed by studies that will no longer be feasible or representative if H.R. 1271 is enacted in its current form. Requiring prior written parental consent is likely to exclude minors who are in trouble with the law or abused at home from studies because parents are not available or willing to provide that consent. Impeding the collection of critical information about the problems affecting children is damaging. Policy makers and law enforce-

ment officials need accurate information about trends affecting children in order to mount appropriate responses to protect child victims and punish young criminals.

Current Federal regulations (45 CFR Part 46, Subpart D) provide protections for minors in research conducted or supported by the Department of Health and Human Services. In addition to requiring confidentiality protections, the rules guard against possible harm that could result from seeking sensitive or inappropriate information. While these regulations do not apply to all federally-funded research, they provide the type of protection needed for minors in survey research, and their more general application can protect minors in research supported by other agencies.

The Department of Justice would like to offer the following amendments in order to remedy the potential harm of this legislation while still ensuring protections for minors: [additions **bolded]**

SEC. 2. FAMILY PRIVACY PROTECTION.

(a) RESTRICTION ON SEEKING INFORMATION FROM MINORS.—Notwithstanding any other provision of law and subject to section 6, in conducting a program or activity funded in whole or in part by the Federal Government a person may not, **require or otherwise seek the response of a minor to a survey or questionnaire without adhering to the provisions of 45 CFR Part 46, Subpart D or** without the *prior written* consent of at least one parent or guardian of a minor or, in the case of an emancipated minor, the prior consent of the minor, require or otherwise seek the response of the minor to a survey or questionnaire which is intended to elicit, or has the effect of eliciting, information concerning any of the following:

This amendment will *require* that *all* federally funded surveys and studies of minors abide by strict regulations ensuring the confidentiality of subjects and protection against possible harm that could result from seeking sensitive or inappropriate information. In research involving human subjects there are inevitably areas specific to each case that blanket legislation would not cover. These cases would be handled on an individual basis under 45 CFR Part 46 through the use of local Independent Review Boards (IRB's).

At a minimum, the Department suggests that the following technical amendments be included: [additions **bolded]**

Sec. 2 (b) **(5) Studies already funded or fielded prior to enactment.**

Sec. 2 (b) **(6) Studies that obtain oral, in person consent from parents or guardians or include the consenting parent as a subject of the same study.**

Sec. 5 **"Guardian" includes a surrogate parent, guardian ad litem, a juvenile court, or persons or agencies responsible for the care, custody, or control of an institutionalized minor child.**

"Emancipated minor" includes a minor considered a "mature minor" and all persons, regardless of age, charged or convicted of a crime after having had juvenile court jurisdiction waived or who are tried or convicted of a crime in other than juvenile court.

Section 4 implies a private cause of action for individuals to sue without any limit on the damages sought. This appears to be contrary to proposed legislation that acknowledges the burden on Federal courts of nuisance suits and seeks to limit damages in Federal and State civil suits. We are concerned that civil court is not the optimum forum to address the vague harm claimed by a prospective parent litigant.

Finally, we note that the language of the bill may effectively extend the restrictions contained in the legislation to activities conducted by or on behalf of the States (to the extent that these activities may be "funded in whole or in part by [a] Federal agency"). We are concerned that such an extension may needlessly interfere with the ongoing efforts of the States to protect children through informed public policy. In addition, State and local governments may incur significant costs due to the additional measures necessary to obtain written consent in activities that do not now require it.

Thank you for the opportunity to present our views on this proposal. Please let us know if we may be of additional assistance in this or any other matter.

Sincerely,

ANDREW FOIS
Assistant Attorney General

cc: Hon. John Glenn, Ranking Minority Member

PREPARED STATEMENT OF DR. LINDA A. TEPLIN, DIRECTOR, PSYCHO-LEGAL STUDIES PROGRAM, PROFESSOR, DEPARTMENT OF PSYCHIATRY, NORTHWESTERN UNIVERSITY

EVANSTON, ILLINOIS
Novemer 13, 1995

Susanne Marshall, *Professional Staff*
Senate Governmental Affairs Committee
340 Dirksen Senate Office Building,
Washington, D.C. 20510

DEAR SUSANNE: Pursuant to our conversation earlier today, enclosed please find three copies of the written testimony of Dr. Linda Teplin, a Northwestern faculty member and the Director of our Psycho-Legal Studies Program. By a letter dated November 10, 1995 and sent to Chairman Stevens, we are submitting this testimony for the consideration of the Senate Governmental Affairs Committee. I have enclosed a copy of that letter.

We continue to oppose the bill and we hope the bill can be amended to provide for exceptions to the rigid rule of written parental consent in all situations. Please let me know of any further developments with the legislation, or of any way in which we can be of assistance regarding the bill. Thank you for your help with this matter, and please do not hesitate to call with questions or comments.

Sincerely,

STEVEN J. BRIDGES,
Associate Director of Government Relations

Attachment follows:

Mr. Chairman, thank you for the opportunity to present my views on H.R. 1271, "The Family Privacy Protection Act". I want to present, for your consideration, a description of my current project on psychiatric disorders among juveniles in custody because it illustrates the problems that would arise if written parental consent were required for all juvenile participants in such projects.

The Northwestern Juvenile Project (Psychiatric Disorders Among Juveniles in Custody) is designed to assess, for the first time, the extent and treatment of psychiatric disorders among juveniles detained by the Nation's justice system. Estimates have been made for the number of juveniles arrested and detained annually in the United States and for the percentage of those juvenile detainees likely to suffer from psychiatric disorders. However, because of the increasing number of youths held within the juvenile justice system, a scientific sample is needed to determine what psychiatric services are required and being delivered.

The U.S. Department of Justice estimates that 2.2 million youths under age 18 are arrested each year. The latest statistics indicate that 570,000 youths were admitted yearly to detention facilities. Juvenile detainees are disproportionately African American, Latino, and poor. Children from wealthier families are rarely detained, probably because their parents are more likely able to get their children diverted from the juvenile justice system when they get into trouble.

Mental health professionals speculate that many youths in detention suffer from psychiatric disorders, and that, once detained, few receive needed services. However, no scientific study has ever assessed the service needs of youth in custody, even though general population studies suggest that as many as 250,000 children in custody at a given time may have a psychiatric disorder and need mental health services. Many detainees are at high risk for developing psychiatric disorders because they suffer from poverty, neighborhood disintegration, parental neglect, and child abuse.

The Northwestern Juvenile Project is the first study of its kind. This study, funded by the National Institute of Health, has two goals: (1) To determine psychiatric service needs among a random sample of 1,800 juveniles in custody; (2) To determine whether youths who need psychiatric services receive them while they are in the custody of the juvenile justice system.

The Northwestern Juvenile Project is the first step needed to implement public policy changes in health service delivery tailored to the needs of the burgeoning juvenile detention population. By law, mentally disordered juvenile detainees must be treated for their disorders, ideally receiving care comparable to what they would receive in the community. Yet, as noted in a recent GAO study ("Mentally Ill Inmates: Better Data Would Help Determine Protection and Advocacy Needs." Washington,

D.C., U.S. Government Accounting Office; 1991), until we have better data demonstrating need, we cannot know how best to use the juvenile justice system's scarce mental health resources. Given the meteoric growth of juvenile detainee populations, data on these youths' psychiatric service needs are increasingly important to improve mental health services, reduce recidivism, and help these disadvantaged children.

Current Federal law allows the Northwestern Juvenile Project to obtain a waiver of the usual parental consent procedures because the research involves only "minimal risk". Minimal risk is defined in current Federal regulations as ". . . discomfort . . . not greater than those ordinarily encountered in daily life or during . . . routine psychological examinations or tests." Current Federal regulations allow waivers of parental consent in research involving minimal risk when it is inappropriate to obtain parental consent (e.g., the detainee has been neglected or abused) or parental consent is infeasible.

The Family Privacy Protection Act would require written parental consent. This requirement is not feasible for studies involving youths in custody. Many children are in detention because their parents could not be found, because their parents have neglected or abused them, or because their parents were not competent to take care of them. Often youths in detention are in a legal limbo, with no contact from their parent, and with no formally appointed guardian who could provide written consent. Many parents of youths in custody have no telephone and are difficult or impossible to locate. Thus, obtaining written consent from such parents is not feasible. If H.R. 1271 were passed, our study would provide no information on psychiatric disorders of the typical juvenile in custody—those who have no parent actively involved in their lives, and who consequently may be at greatest risk for developing psychiatric disorders and other behavior problems.

I understand that the impulse behind H.R. 1271 is to shield minors from exploitation by inappropriate research. However, in the case of "minimal risk" research, the proposed requirement of written parental consent is not only infeasible but unnecessary. Under current law, when consent cannot be obtained from a parent, it is obtained from the juvenile by the following procedure. Before a research project can even be submitted to a Federal funding agency, an Institutional Review Board (IRB) must approve the research protocol and the procedures of assuring confidentiality of the subjects, weighing the risks and benefits of such research. Each IRB stringently reviews any research protocol involving children or adolescents. It may require written parental consent or, if it judges the research to be of minimal, risk, it may allow another consent procedure. However, the IRB standard is "informed consent" of all participants. For example, in our study on juvenile detainees, parents are often either no longer involved with the child or incapable of giving an informed consent due to substance abuse or mental health problems. We make a 24-hour effort to reach the parent of the detainee. If unsuccessful, we then have the juvenile interviewed by a participant advocate to determine if the minor is competent to give his or her consent to the research. If so deemed, the juvenile is asked to sign a waiver. This type of flexibility would be lost under H.R. 1271. Given the non-invasive nature of "minimal risk" research, this procedure provides quite adequate protection to the juvenile subjects.

In conclusion, the written parental consent requirement is both impracticable and unnecessary for a large segment of the juveniles detained by the justice system. Furthermore, this requirement would prevent research, like the Northwestern Juvenile Project, designed to help that segment of the juvenile population, which has significant psychiatric needs that can only be addressed efficiently and effectively in light of information obtained by such research. I recommend legislation that strengthens parental consent, but that still allows case-by-case attention to particular situations and local concerns, and that still provides for Institutional Review Boards, using "informed consent" as their standard, to review and approve research and consent protocol for studies involving children. I hope, Mr. Chairman, that you and your Committee will give my testimony due consideration and see the wisdom of allowing flexibility in obtaining the parental consent of children in difficult situations.

PREPARED STATEMENT FROM THOMAS J. GLEATON, ED.D., PRESIDENT, PRIDE

November 8, 1995

Senator Ted Stevens, *Chairman*
Senate Governmental Affairs Committee
340 Dirksen Senate Office Building
Washington, D.C. 20510

DEAR CHAIRMAN STEVENS: We respectfully request that you insert the attached statement in the written record of the November 9, 1995 hearing on the Family Privacy Protection Act. This statement is written by the National Parents' Resource Institute for Drug Education in opposition to the said Act.

Sincerely,

THOMAS J. GLEATON, ED.D.
President

Attachment follows:

The National Parents' Resource Institute for Drug Education (PRIDE) was founded to assist parents in the United States to raise healthy and drug-free youth. The PRIDE Parent Training model has been adopted in 847 communities in the United States. Some 11,603 PRIDE volunteer trainers have provided 6 million hours of training to more than 750,000 parents.

We are writing in opposition to the Family Privacy Protection Act of 1995 (H.R. 1271). The bill would require active consent of parents before drug survey responses could be sought from students. Even if the survey is completely anonymous and voluntary, signed and written consent of the parent would be necessary.

If this legislation is signed into law without significant change, parents in America could loose one of the most important public health indicators: The reporting of the local and national dimension of the adolescent drug use problem. Ironically, this action would come at the same time that PRIDE is reporting that two-thirds of parents are not communicating often with the children about drugs.

In 13 years of the PRIDE Survey we have received few complaints from parents even though more than 7 million students have responded to the survey. One group which has objected loudly to the PRIDE Survey is the drug legalization lobby. In the April 20, 1990, edition of the *Atlanta Constitution,* a spokesman for the Drug Policy Foundation claimed that PRIDE uses its survey to "drum up a lot of hysteria" against marijuana and other drugs. Drug Policy is a Washington-based pro-legalization group.

The PRIDE Survey is administered anonymously and is voluntary. Students are not compelled to complete the survey instrument. Notice is often given through school board meetings, announcements in the press, and notices sent home to parents. Copies of the instrument are made available to the public for inspection. Many school systems report their data to the public by means of press releases and press conferences.

Requiring parental consent would:

- add greatly to the cost of administration of the survey
- place an undue burden on the school staff
- contaminate research findings
- likely kill local efforts to assess drug problems and evaluate programs
- represent an unfunded Federal mandate to local education agencies

The greatest negative impact of the parental consent act could be felt by local organizations at a time when responsibility for solving the drug problem is being shifted to the states.

It is important for the Senate to understand that national surveys can be conducted most efficiently and cost effectively by a sampling method. However, local surveys can be more efficiently and economically administered by a census method, for example, when studying students in a single school building or small school district In the latter case, it is less costly to survey every student than to design a sample, and the results of a census study are more reliable.

Federally-funded research projects which strive for a national sample could possibly afford the added costs of parental consent. But users of the PRIDE Survey are typically small school systems and community-based organizations. They pay only 86 cents per student to conduct a PRIDE Survey. That cost would rise 64 cents in postage alone if a First Class notice and stamped return envelope is required. Add the cost of handling and re-contact for non-responses, and the cost would more than double. In addition, the administration time would also more than double—effec-

tively killing the ability of local programs to conduct the survey. To require active consent of every parent would render useless this method of data collection, the most common method of local, action-oriented research.

PRIDE believes the threats that are posed by the Family Privacy Protection Act were unforeseen and unintended by the Congress, especially Members who won election last November on the appealing message that local problems are best solved by local solutions. In the past week alone, PRIDE has seen a number of Senators refer to rising drug use rates detected by the PRIDE Survey. It is clear to us that our ability to collect these data will be severely limited if this proposed legislation becomes law.

We urge the Senate:

- to exempt the PRIDE Survey and other legitimate, local and national drug use surveys from the act,
- or, to provide that the act apply only to "research beyond minimal risk," and
- or, to defeat the Family Privacy Protection Act as written.

PREPARED STATEMENT FROM DOUG HALL, SENIOR VICE PRESIDENT, PRIDE

November 14, 1995

Senator Ted Stevens, *Chairman*
Senate Governmental Affairs Committee
340 Dirksen Senate Office Building
Washington, D.C. 20510

DEAR CHAIRMAN STEVENS: We request that you insert the attached letter, signed by 30 organizations, into the written record of the hearing on the Family Privacy Protection Act held on November 9, 1995.

Thank you.

Sincerely,

DOUG HALL
Senior Vice President

Attached letter follows:

November 14, 1995

The Hon. Ted Stevens, *Chairman*
Senate Governmental Affairs Committee
340 Dirksen Senate Office Building
Washington, D.C. 20510

DEAR SENATOR STEVENS: We, the undersigned organizations, represent a broad spectrum of the alcohol, tobacco, and other drugs field in the United States. We are comprised of local, State, and national organizations that promote the prevention, intervention, and treatment of substance abuse problems in the Nation.

We are writing to express our opposition to the Family Privacy Protection Act, which is now being considered by the Senate Governmental Affairs Committee.

Many of the organizations whose names appear on this letter are themselves comprised of parents, youth, and grass roots community leaders. We are organizations which have accumulated many years of experience in strengthening the family unit system, in helping parents raise their young, and in providing young people with the opportunity to live safe, healthy, and drug-free lives.

In short, we are organizations that want nothing less than protection for families. Yet it is our conclusion that the proposed Family Privacy Protection Act will have the unintended consequence of hurting the American family, and American children.

If this legislation is passed into law, we foresee the end of meaningful data collection about drug use among the Nation's young. This information has been a warning system for parents and families during the past two decades of roller coaster drug use levels. It has alerted parents to isolated drug trends (for example, the rise in LSD use first detected in 1989), and it has kept a focus on overall drug use at both the local and the national level. The reporting of drug usage rates by young people has also been a determining factor in quieting the siren call for drug legalization.

Above all, this is not the time to hamper drug prevention and treatment efforts in the country. Every national survey indicates a recent surge in adolescent drug use. This includes the University of Michigan Monitoring the Futures Survey, the National Household Survey, the PRIDE Survey, and DAWN.

The Family Privacy Protection Act would adversely affect data collection in two primary ways:

(1) The requirement for written parental consent would place insurmountable economic and procedural burdens on the ability of groups to collect vital survey data. This would be a particular problem at the community level where funds are already limited and capacity is stretched.

(2) The reliability and validity of data would be adversely affected. This is the conclusion of the vast majority of research professionals. And it is our conclusion after carefully studying the issue.

Finally, the Family Privacy Protection Act attempts to correct a problem that does not exist in the context of alcohol, tobacco, and other drug surveys. Dr. Lloyd Johnston, principal investigator of the Monitoring the Futures Survey, said that his experience since 1975 indicates that only 1 to 4 percent of parents object to their children taking part in drug surveys. Dr. Thomas J. Gleaton author of the PRIDE Survey, said he has received only a handful of parental complaints in 13 years even though his organization has surveyed some 7 million students.

We believe that any real or perceived privacy intrusions can be alleviated without depriving the Nation of vital drug use indicators, and we would respectfully request that the Senate Governmental Affairs Committee work with us to develop such alternative solutions.

Thank you for your considering our views. Please feel free to contact Doug Hall of PRIDE at 770–458–9900 if you have any questions.

Sincerely,

African American Parents for Prevention, Inc.
American College of Nurse Practitioners
American Public Health Association
American Youth Work Center
American Methadone Treatment Association, Inc.
Betty Ford Center
Center for Alcohol and Drug Research and Education
Center for Science in the Public Interest
Community Anti-Drug Coalitions of America (CADCA)
D.A.R.E. America
Developing Resources for Education in America, Inc. (DREAM)
Elks Drug Awareness Program
Entertainment Industries Council, Inc.
Florida Informed Families
National Asian and Pacific American Families Against Substance Abuse (NAPAFASA)
National Families in Action
National Association for Children of Alcoholics
National Association of Alcohol and Drug Abuse Counselors
National Association of Prevention Professional and Advocates (NAPPA)
National Association of State Alcohol and Drug Abuse Directors (NASADAD)
National Council on Alcoholism and Drug Dependence
National Family Partnership
National Parents' Resource Institute for Drug Education (PRIDE)
National School Boards Association
National Treatment Consortium for Alcohol and Other Drugs
Ohio Parents for Drug-Free Youth
Partnership for a Drug-Free America
Physicians for Prevention
Prevention, Intervention and Treatment Coalition for Health (PITCH)
Tennessee Family Partnership
Therapeutic Communities of America

PREPARED STATEMENT FROM SHIRLEY IGO, NATIONAL PTA, VICE-PRESIDENT FOR LEGISLATION

The National PTA thanks the Chairman and Members of the Senate Committee on Governmental Affairs for this opportunity to present our views on H.R. 1271, the Family Privacy Protection Act. The National PTA is a nonprofit association comprised of over 6.9 million parents, teachers and other child advocates concerned with the education, health and protection of children and youth. In addition, the National PTA believes that parental involvement at all levels of decision-making is essential in developing wise and effective policies. The National PTA opposes H.R. 1271 as passed by the House, but offers suggestions that will provide for parental involve-

ment while allowing for meaningful and scientific data collection related to and about the condition of our children.

If the goal of H.R. 1271 is to involve parents more directly in any fully or partially Federal funded "survey, analysis or evaluation" conducted with minors, that is indeed laudatory and supported by National PTA legislative and programmatic authority. By including federally financed surveys in H.R. 1271, whether undertaken by an agency of government or by researchers using Federal money, becomes an expansion of current law. Whether or not there is evidence of questionable surveys being administered to children and youth in the public schools, the National PTA believes that a parent has a "right to clear and complete information about the school. . . ."[1]

At the same time, "the National PTA supports Federal legislation to extend and support research focusing on the needs of children and families."[2] Information that contributes to more effective polices related to such child and family related issues as substance abuse, student assessment data, violence, adolescent pregnancy, educational reform, funding and HIV/AIDS should be gathered around a research construct that is valid, scientific and objective. The National PTA, therefore, has an interest in bringing together and bridging the rights of parents to be involved in research determination of their children with society's compelling interest in conducting and receiving sufficient information to make wise policy decisions about our young people. A major National PTA legislative policy is "to encourage parental involvement as an essential part of the PTA mission by promoting an environment in which parents are valued as primary influences in their children's lives and essential partners in their children's education and development."[3] In this respect, parents should have the right to know when their children are being surveyed, the nature of the survey and guarantees that their children's privacy rights will be protected. We have also been told of the administration of surveys that parents found objectionable on one or a number of grounds including the topical nature of the survey, the questions asked, or the use to which the answers to the question would be put. These issues usually related to such controversial subject areas as sex, political affiliations, parental attitudes, values and homelife. Parents who most often objected to certain surveys also have indicated that they met with resistance from school officials when they sought to exclude their children from certain research they found personally objectionable.

On the other hand, the National PTA believes that "the role of the Federal Government in support of education must include investing in research and development to improve the quality of education."[4] The Research and Privacy Coalition states that with the current proposal requiring researchers to secure "written parental consent" before minors can be involved in any Federal research study or sampling, this language would greatly deter the ability of many researchers to secure an adequate sampling or afford the cost of such written permission.[5] As this Committee is obviously aware, schools cannot release information about parents to researchers, and the schools therefore must bear the burden of contacting parents and following-up on the responses. Where schools have the personnel to conduct this outreach, research costs will automatically increase due to the written permission requirements which also increase the regulatory burden.

Clearly, research provides valuable information relied upon by educators, families, policymakers, health care providers and private sector groups. The National PTA relies heavily on data collected by a variety of sources including the Centers for Disease Control, the National Center for Educational Statistics, the National Assessment for Educational Progress and Monitoring the Future which has been surveying 12th grade students for over 20 years (and 8th and 10th grade students for the past five years) related to drug, alcohol and other substance abuse. The National PTA uses research information in developing its positions and passing resolutions, reconciling research data related to specific legislation and rules and regulations, and providing parents with baseline measurements about how their community compares with others in the health, environment and education arena. This information serves to empower parents and provide accurate documentation in becoming involved as advocates of children. It would be a disservice to policymaking if this qual-

---

[1] National PTA Position Statement on *Parent Involvement: Individual and Organizational Rights and Responsibilities in the Development of Children,* 1991.

[2] *National PTA Legislative Program 1995–1996.*

[3] *National PTA Legislative Program, Education Policy No. 6, 1995–1996.*

[4] National PTA Position Statement on *Governmental Responsibility for Education* affirmed 1993.

[5] Testimony of the Research and Privacy Coalition before the Senate Committee on Governmental Affairs, November 9, 1995.

ity research were "chilled" as a result of overly burdensome requirements, or findings compromised as a result of biased samplings.

Parental concerns about Federal research is not new, and H.R. 1271 is but one of several initiatives in attempting to find the correct balance between the society's interest in research and parents' concerns about the research questions, methods and content. For purposes of this statement, it would help to summarize what is already law:

The General Education provisions Act (GEPA) was originally enacted in 1967 at Title IV of the Elementary and Secondary Education Amendments, which consolidated into a single provision all of the statutory requirements of the past 100 years. All of the parental privacy acts have been attached to GEPA as amendments. These amendments are:

The "Kemp" amendment of 1974 requires that parents of pupils participating in federally-assisted research projects be provided access to the instructional materials. Subsequent to passage of the amendment, the National PTA monitored the implementation of this amendment and helped to inform parents of their rights.[6]

The "Hatch" amendment, known as the Family Privacy Protection Act, required prior consent of the pupil (if an adult or emancipated minor) or the pupil's parent/guardian and referred to specific areas of inquiry such as political affiliations, mental or psychological problems, sexual behaviors or attitudes; illegal, anti-social or "demeaning" behavior, privileged relationships, income or critical appraisals of family members. The National PTA supported the amendment's provisions related to the confidentiality of school records.[7]

The Grassley amendment passed in 1994 expanded consent requirements to "any survey, analysis, or evaluation" that was federally-assisted and mandated written consent. The National PTA opposed the written mandates requirements and the expansion until it could be determined that the intent of the previous two amendments were being egregiously circumvented by local school districts and the Federal Government. In other words, the National PTA did not disagree with the motives, but questioned the necessity and asked for documentation to prove that expanding the scope of Kemp and Hatch was warranted by evidence of noncompliance. From National PTA's standpoint, there were inadequate Hill hearings and debate to address the amendment which was attached to Goals 2000. The National PTA ultimately supported Goals 2000, primarily because of the addition of a new national education goal which pertained to parental involvement.

At issue, than, is the provision that requires written parental consent—whether this requirement is necessary beyond anecdotal information, and whether parents would be better served by the provision. The National PTA believes that parents should have the right to examine the survey their children are asked to take, that parents be able to prohibit their child's participation in a survey they find objectionable, and that parents have a right to know how that information will be used. However, the National PTA opposes the requirement of *written* consent of all parents before a child may participate in a survey. This requirement is unnecessary to meet the goal of parental involvement, and in the case of some parents, the requirement might create a barrier. The House Committee on Government Reform and Oversight also recognized this fact by dropping the written consent requirement. It was reversed on the House floor, however.

The provision of written consent should be dropped for the following reasons:

1. It will create an administrative burden for many school districts;
2. For various research projects, there may be more appropriate means of obtaining meaningful parental consent, such as face to face meetings for parents who do not read in the language of the consent form and parents giving consent over the phone;
3. Parents may not return the form, not because they object to the research, but because they may not have the time to fill out the form;
4. The cost of administrating the consent procedures may be prohibitive for the parties bearing the cost, either the researcher or the school;
5. Response rates may be unacceptably low or the sampling skewed which may bias research results.

At this point, the National PTA believes that further documentation and study is necessary by the General Accounting Office to demonstrate that an expansion which H.R. 1271 would allow warrants the cumbersome process created by the written consent requirement.

---

[6] National PTA *What's Happening in Washington,* 1977–78 Legislative Priorities.
[7] National PTA Position Statement revised and reaffirmed in 1981 and 1987.

The National PTA thanks the Committee for this opportunity to submit comments.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PEDIATRICS

The American Academy of Pediatrics is an organization of 50,000 pediatricians dedicated to promoting the health, safety and well-being of all infants, children, adolescents and young adults. This statement reflects the Academy's positions on H.R. 1271, "The Family Privacy Protection Act of 1995."

Providing pediatric care of the highest quality is the paramount goal of the Academy's physicians. Improving the physical, mental and social health of all children and adolescents is only possible, however, when there is sufficient research and data available on the attitudes and behaviors of our Nation's youth. It is this source of vital information which is threatened by this bill, and is therefore the basis of our concern with H.R. 1271.

"The Family Privacy Act of 1995" requires written parental consent for all confidential surveys of minors conducted by all federally-funded government programs. On its face this appears to be a harmless requirement which enhances parental involvement and control over questions or information requested of minors. We believe, however, that in reality, its implementation will cause valuable and important scientific research to be significantly compromised. The Academy is deeply concerned about the negative effects this legislation would have on the ability of parents, medical professionals, school personnel and other individuals to monitor, understand, collect and analyze vital research data and to address crucial problems faced by the Nation's youth. As physicians and researchers, in order to address the high-risk behaviors in which children and adolescents engage (i.e., tobacco use, violence, drug and alcohol use and other health risks) it is essential that we understand the prevalence of the activities. Limiting the participation in a survey to only those students or youth whose parent or guardian has provided written consent risks biasing the scientific outcome of such a survey. For this reason, the Academy cannot support this bill as currently written.

The Academy strongly believes that parental consent for a minor to participate in research should be the standard. It is the mandate of written parental consent which we find troubling. A single mechanism for obtaining parental consent denies the opportunity to use more effective procedures. This provision makes a false assumption that "written" consent is synonymous with "informed" consent. Requiring written consent does not always ensure that parents are fully informed of the benefits and risks of a child's participation in a research study. Suppose, for example, a parent has a language barrier; written consent does not provide an opportunity for them to understand the privacy protections that are part of current law.

A further concern is that time-consuming and expensive follow-up is required to secure written parental consent, which still may not be effective in procuring a representative research sample. Furthermore, those least likely to obtain written parental consent may well constitute a disproportionately high percentage of the at-risk adolescent population. With these data excluded from studies, results would become highly biased, and diminished in their usefulness.

It is important to note that at present there are already existing Federal guidelines and regulations in place that assure research subjects are informed of any risks and benefits of proposed research. These requirements are tailored for youth participants so that they and their parents are informed about the study, and informed consent is obtained for the youth's participation. Research subjects are also given sufficient information about the research to decide whether or not to participate.

Any proposed research project conducted by Federal grantees must be reviewed and approved by official Institutional Review Boards (IRBs) whose deliberations, in turn, are guided by Federal laws and regulations regarding the use of human subjects in scientific research. IRBs as well as the regular peer review process at the Federal agencies are designed to ensure that a research plan involving young subjects include a method to inform potential subjects and their parents about the study.

In an age where the social and societal ills facing our Nation's children and adolescents is rising dramatically, the pediatric community relies on research in such areas as violence, suicide, delinquency, and the use of alcohol, tobacco, and illicit drugs. It is well known that adolescents are reluctant to discuss risk-taking behaviors with their parents. How will we know how to help our children if we don't understand the behaviors in which they are engaging?

In summary, "The Family Privacy Protection Act of 1995" will likely have a significant adverse impact on crucial research and data collection pertaining to the attitudes and behaviors of our Nation's youth. The American Academy of Pediatrics strongly urges Congress to emphasize that "informed" consent for participation in research must be obtained. The specific means by which this consent is obtained should include, but not be limited to, only the option of written consent. Consent should fit the specific purposes and population of any proposed study.

We further urge Congress to recognize the importance of having valid, useful research and data regarding our most vulnerable population—the Nation's youth. As local, State and Federal policies are crafted to protect our children from participating in high risk behaviors, having comprehensive research is vital to assist Congress and other policy-makers.

National Fatherhood Initiative
600 Eden Road, Building L • Lancaster, PA 17601
(717) 581-8860 • (717) 581-8862 FAX • (800) 790-DADS

11/30/95

The Honorable Ted Stevens
Chairman
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510-6250

Dear Senator Stevens:

Attached are my written answers to the post-hearing questions submitted by Senator Glenn as a follow-up to the hearing on November 9, 1995, concerning H.R. 1271, the Family Privacy Protection Act. Should you have need to contact me further concerning these answers, I can be reached at 301-948-0599.

Again, I want to thank you for the opportunity to testify in support of H.R. 1271, and hope that you will not hesitate to contact me again should I be in a position to be of help to you.

Sincerely,

Wade F. Horn

Wade F. Horn, Ph.D.
Director, The National
Fatherhood Initiative

Post-Hearing Questions from Senator Glenn
for Wade Horn

1. I think it is very important to families and society to get reliable information on serious problems like alcohol and drug abuse, crime and violence, mental health, and other youth issues. Do you agree? Should the Federal government support research into these subjects?

> I believe it is important to obtain reliable information on serious problems facing our nation. I also believe the Federal government should support research into such matters. But in a free society, which values individual liberties, a scientist's license to ***require*** someone's participation in his or her study must necessarily be limited. Even if we can all agree that there is value to the information being sought, one is not justified in compelling participation unless to do otherwise would place the individual's well-being in jeopardy. In the case of children, the ethical requirement to obtain prior consent from a competent adult whose primary interest is the welfare of the child, is even more compelling. More, not less, safeguards should be the rule when dealing with children as potential participants in research.
>
> In addition, it is simply not true that the adequacy of the sample is the only source of unreliability in survey research. Other sources of measurement error, such as faking bad (or good), random responding, and miscoding of data, all potentially contribute to unreliable data. Ensuring an adequate sample does ***not***, in and of itself, result in reliable information.

2. An across-the board written consent requirement would in many cases require extensive follow-up by researchers. This would substantially raise the costs of research and significantly lower response rates simply because of difficulties in contacting parents. This could eliminate much needed research into at-risk children's issues. Please describe the specific harm to children and families that would justify the loss of such research, and/or describe the extent to which you disagree with these statements.

> The cost of the survey or questionnaire is not the concern of the potential participants. It is the concern of the researcher. As such, the cost of conducting the survey or distributing the questionnaire is simply ***irrelevant*** to the ethical requirement to fully inform the potential participant (or in the case of children, his or her parent or legal guardian) as to the purpose and particulars of the survey or questionnaire. To maintain otherwise would be to place the cost of research on the same level of concern as the welfare of the research participant. Without a doubt, it would be far cheaper for researchers to conduct research without having to obtain consent; but the same could be said for other ethical requirements, such as ensuring the safety of the participant, maintaining confidentiality, or debriefing following the study. Cost considerations must not be allowed to justify unethical research practices.

3. Federal guidelines currently protect the anonymity of survey responses. Do you have any specific examples of that anonymity being violated?

Although I do not have personal knowledge of an instance where the anonymity of survey responses has been violated, that does not mean that there have been no such violations. Whether or not there have been such violations of anonymity is, however, irrelevant to the ethical requirement to obtain informed consent prior to including someone in a research undertaking. Otherwise, investigators would be empowered to undertake any kind of research, no matter how repugnant to the participant, so long as the data were kept anonymous and confidential. Obviously, such is not the case. Informed consent is necessary ***before*** including someone in a research study. Issues of anonymity and confidentiality are relevant ***after*** an individual (or in the case of children, his or her parent or legal guardian) has agreed to participate in the study.

CHRISTIAN COALITION *of Alaska*

Date December 5, 1995

To Susanne Marshall
Senate Committee on Governmental Affairs

From: Art Mathias
President of Christian Coalition of Alaska

RE: Post hearing questions from Senator Levin on H.R. 1271, Family Privacy Protection Act

Question 1: In your testimony, you cited a survey given in a social studies class entitled, " Are you a Conservative or a Liberal?" Please indicate whether this was a citywide, statewide, or nationwide survey. Who sponsored the survey? Was it federally funded? Did the survey violate Alaskan or federal law?

The survey entitled "Are You a Conservative or a Liberal?" is included as a supplement to a political science unit in the Bostingl textbook entitled "Introduction to the Social Sciences". It is the textbook used in the Anchorage School District for 8th grade Social Studies. It is used citywide. I do not know if this particular textbook is in use in other Alaska school districts or what other states use it. Textbook purchase is the financial responsibility of the individual school district.

This survey, in my opinion, violates both Alaska and Federal law. Alaska law (see attached copy) under Section 14.03.110 specifically requires written permission before a school district, principal or other persons in charge of a public school, or teacher in a public school may administer or permit to be administered a questionnaire or survey that inquires into private family affairs of the student not a matter of public record.

Federal law proposed under H.R. 1271 or the Grassley Amendment to goals 2000 would also require a prior written consent of at least one parent to require or otherwise seek the response of a minor to a survey or questionnaire in certain areas. Political beliefs of the parents is the first area listed.

The Anchorage School District lawyers say the survey was not "required" so the law was not violated. They conveniently forget to read the balance of the sentence that says "or otherwise seek the response of the minor."

The regulators and bureaucrats often play games with words to twist the intent of the law to their purpose and agenda. Therefore it may be very important to make the language as clear and simple as possible.

Question 2: If the questionnaire had been developed by a single teacher for a single class, in a school that receives federal funding, and given without written parental consent, would this constitute a violation of H.R. 1271?

In my opinion, yes it would. Any school that receives Federal Funding is by law a "recipient" therefore subject to federal rules, regulations and laws. The intent of this law is to protect students and families from invasions into private matters. It should not matter if it is a "single teacher for a single class" or whether the questionnaire/survey is adopted nationally. It is still an invasion of privacy that H.R. 1271 specifically forbids.

Family Research Council®
Gary L. Bauer, President

November 29, 1995

Senator Ted Stevens
Committee on Governmental Affairs
U.S. Senate
Washington, D.C. 20510-6250

Dear Senator Stevens,

In regards to testimony I gave on November 9, 1995 about H.R. 1271, the Family Privacy Protection Act, Senator Levin posed the following question:

> "In response to a question from Senator Stevens, you cited survey questions that asked children to elaborate on the nature and frequency of same-sex sexual contact that they have experienced. Please identify this survey, and state who sponsored it and whether it was federally funded. Please provide the questions to which you referred."

The specific survey I referenced was the $18 million "teen sex survey" drafted by the National Institute of Child Health and Human Development. The project was approved in 1991 by the Assistant Secretary for Health, Dr. James O. Mason, and by Dr. Bernadine Healy, the director of the National Institutes of Health. The questions to which I referred are as follows:

- *Have you ever rubbed another male's sex organs to sexually excite him?*
- *If you ever put your penis in another male's rectum or another male ever put his penis in your rectum, was a condom used?*

We don't have a copy of the actual survey, but Sen. Levin's office should have no problem securing one from the NICHHD. I have, however, attached a copy of a *Washington Times* article about the survey. If you have any further questions, please contact me.

Sincerely,

Robert H. Knight
Director of Cultural Studies

cc: Senator Levin

The Washington Times

July 19, 1991, Friday, Final Edition

SECTION: Part A; Pg. A1

LENGTH: 1305 words

HEADLINE: Surprised Sullivan says 'whoa' to teen sex survey

BYLINE: Joyce Price; THE WASHINGTON TIMES

BODY:

Health and Human Services Secretary Louis Sullivan was kept in the dark about an $18 million sex survey of American teen-agers and ordered a temporary halt to the study yesterday after learning about it.

An HHS spokesman said Dr. Sullivan knew nothing about the survey until Tuesday, when he was asked about it during a televised interview on the conservative Coalition for America's satellite network. The secretary put the project on hold until he learns more about it, the spokesman said.

"He was absolutely surprised by this and unpleased something like this could be happening without his knowledge," coalition co-chairman Michael Schwartz said yesterday.

The teen sex survey, which had progressed to the point of hiring interviewers, was being undertaken by the National Institute of Child Health and Human Development just two years after Congress killed most of the funding for a $14 million national sex survey of adults.

"This is a large, national study of adolescent behaviors that put young people at risk for unintended pregnancy and sexually transmitted diseases," NICHHD Director Duane Alexander wrote recently to Rep. William Dannemeyer, a conservative California Republican.

But Mr. Dannemeyer and leaders of several conservative Christian and pro-family groups are outraged that federal money will be spent to interrogate thousands of adolescents in grades seven to 11 about sexual activities - both homosexual and heterosexual - as well as contraceptive use, pregnancy, abortion and sexually transmitted diseases.

Paul Mero, spokesman for Mr. Dannemeyer, said everyone should be upset about some of the questions in draft copies of the survey obtained by the congressman.

One question on the draft of the questionnaire for boys "asks the teen-ager if he's ever had a penis up his rectum," Mr. Mero said. Next to the word rectum, in parentheses, is a vulgar term for rectum for teens who might not know the word, he said.

The Washington Times, July 19, 1991

When told some of the questions that appear on the draft questionnaires, Gary Bauer, spokesman for the Family Research Council, said yesterday: "I don't feel federal bureaucrats should be spending federal dollars for a survey that offends the sensibilities of millions of Americans."

Concerned Women for America and the Rev. Pat Robertson's Christian Coalition also expressed outrage and made it clear they'll alert their memberships to the poll's existence.

"It's outrageous that millions of our tax dollars are going to be spent to ask seventh-graders if they've experienced oral and homosexual sex acts," said Beverly LaHaye, president of Concerned Women. "This is a totally inappropriate use of government funds."

First-year funding for the survey, which is to be directed by researchers at the University of North Carolina in Chapel Hill, was provided in the form of a $2.4 million NICHHD grant awarded in May.

"Due to its sensitive nature, the project was . . . approved by the Assistant Secretary for Health [Dr. James O. Mason] and by the director of NIH [National Institutes of Health], Dr. Bernadine Healy," Dr. Alexander said in his letter to Mr. Dannemeyer.

"This is the same kind of nosy intrusion into people's private lives that we opposed in the adult sex survey," Mr. Mero said. "Our goal will be to wax this study like we did the adult study."

He said the child health institute had been seeking funds for the teen sex survey two years ago but dropped it because of the flap over the adult sex survey. Congress cut $11 million off the $14 million funding for the adult poll.

Mr. Mero expressed optimism in the new battle.

"We're confident George Bush doesn't want to be known as the sex president and that Dr. Sullivan doesn't want to be an accomplice," he said.

Michaela Richardson, spokesman for NICHHD, said the study is designed to gather information about behavior that puts teens at risk for AIDS, unintended pregnancies and venereal diseases.

"But it deals with all aspects of adolescence, including school and family experiences, friends, and community environment," she said. "It will be trying to see which factors work together to put young people at risk."

Questions about religious attitudes and use of tobacco, alcohol and drugs also would be asked, she said.

A total of 24,000 teen-agers would be studied with their permission, Mrs. Richardson said. "And parents have to agree before any young person can participate," she added.

But Mr. Mero said this condition ensures built-in bias in the survey. "Just think of the people who'd allow their kids to participate in a survey like this," he said.

The Washington Times, July 19, 1991

The in-depth interviews would be conducted at teens' homes, according to the draft questionnaires. "The questionnaires will be designed to ensure that an adolescent is asked only those questions that are appropriate to his or her experience," Dr. Alexander wrote to Mr. Dannemeyer.

Some homosexual groups also are concerned about the study, since it would ask teens to name their sexual partners. Mrs. Richardson said rigorous steps would be taken to ensure confidentiality. Names and identifying information would be kept separated from the interview data and locked in a secure location, she said. "The information will not be accessible under the Freedom of Information Act and could not be subpoenaed," she said.

But Gregory King, communications director of the Human Rights Campaign Fund, the nation's largest homosexual group, said assurances of confidentiality often prove meaningless.

Just as NICHHD didn't give up on the teen sex survey, it hasn't abandoned the adult sex survey, either. "The adult study is not dead," Mrs. Richardson said.

The House deleted the institute's request for $3 million for the adult survey in fiscal 1992, but the funding remains in the appropriations bill on the Senate side.

"This is like killing cockroaches," Mr. Mero said. "You turn on the light and you might nail one. But the other 50 escape, wait until the light goes off again and they come out."

****BOX

TEEN-AGE SEX STUDY

This survey, devised by the National Institute of Child Health and Human Development, a federal agency, would be administered to 24,000 children in grades 7 to 11.

The questions are about these five sex practices:

1. Sexual intercourse (penis in vagina)

2. Oral sex - Your mouth was on your partner's genitals (private parts, not including breasts)

3. Oral sex - your partner's mouth was on your genitals (private parts)

4. Your penis was in your partner's rectum

5. Your partner's penis was in your rectum

Other questions

For girls

* Have you ever been pregnant?

The Washington Times, July 19, 1991

* Have you ever thought you were pregnant, but it turned out you weren't?

* In what month and year did you have sex that led to this pregnancy scare?

* How many different men have got you pregnant?

* Have you ever had a condom (or vaginal sponge, birth control pills or diaphragm) in your possession?

For boys

* Have you ever got someone pregnant?

* How many times have you got someone pregnant?

* How many different girls have you got pregnant?

* Have you ever rubbed another male's sex organs to sexually excite him?

* If you ever put your penis in another male's rectum or another male ever put his penis in your rectum, was a condom used?

For both sexes

* Indicate how good or bad you think each of seven listed methods of birth control is in terms of its effectiveness in preventing pregnancy, health risks, sexual spontaneity, and ability to prevent sexually transmitted diseases.

* Did you ever force someone to have sex with you against her or his will?

* Have you ever been given drugs in exchange for having sex?

GRAPHIC: Box, TEEN-AGE SEX STUDY, By The Washington Times

LANGUAGE: ENGLISH

POST-HEARING QUESTIONS FROM SENATOR GLENN FOR MR. HILTON

December 1, 1995

Senator Ted Stevens, Chairman
U.S. Senate Committee on Governmental Affairs
Room 340 Dirksen Senate Office Building
Washington, D.C. 20510-6250

Re: H.R. 1271—Follow up Questions from Senator Glenn

DEAR CHAIRMAN STEVENS: I am in receipt of your request to respond to three post-hearing questions from Senator Glenn.

This letter and the enclosed affidavits represent my response to those questions. Each question is listed below and my response thereto.

Question 1. I think it is very important to families and society to get reliable information on serious problems like alcohol and drug abuse, crime and violence, mental health, and other youth issues. Do you agree? Should the Federal Government support research into these subjects?

The question appears to presuppose that families and societies need the same type of information and that the information would be secured in the same way for both entities. I agree that families and government entities may well want this information, but disagree that any perceived societal need compels parents and their children to provide on governmental demand any and all research that could be desired by the government. As to legal theory, for reasons cited in my written and oral testimony, it is my considered opinion that such intrusion without adequate disclosure to parents or without their consent violates prohibitions contained in the Federal constitution. As to actual practice, the information provided to the Senate over several decades when adopting 20 U.S.C. § 1232h as well as my experience in both litigation and drafting State legislation on family privacy matters indicates that there are many parents and families that do not agree that federally funded efforts to obtain certain types of information are either desirable, necessary, or lawful.

It is obvious that the Federal Government is providing significant funding for research into social issues at this time. I do not expect present Federal funding to a particular project to change because of this hearing or this legislation. As there are no funding proposals that are included in H.R. 1271, I am unable to properly respond in more detail to a broad question regarding the desirability of government funded research into undefined areas of social concern without greater clarification of the ends specifically desired and the appropriateness (both in terms of research design and costs) of the means chosen to achieve those ends. The broad societal concerns are appropriate issues for Federal, State and local governments to consider; however, actual change and ultimate resolution of the challenges will only occur on an individual, parental and familial level.

Question 2. An across-the-board written consent requirement would in many cases require extensive follow-up by researchers. This would substantially raise the costs of research and significantly lower response rates simply because of the difficulty of contacting parents. This could eliminate much needed research into at-risk children's issues. Please describe the specific harm to children and families that would justify the loss of such research, and/or describe the extent to which you disagree with these statements.

I fundamentally disagree with the first three statements of your question. It appears to me that both legal theory and practical reality compel a contrary position. In legal theory, governmental agencies generally are required to protect parental autonomy and parental privacy when testing minors. Governmental regulations require both detailed informed consent as well as document of informed consent. (Examples of these regulations for various departments include the Department of Education, 34 C.F.K Subtitle A, §§ 97.116, 97.117 (7–1–95), Department of Energy, 10 C.F.R. Ch. III §§ 745.116. 745.117 (1–1–95), Environmental Protection Agency, 40 C.F.R. Ch. I §§ 26.116, 26.117 (7–1–95), and those referred to in the Affidavit of Dr. Adrian Van Mondfrans from the Office for the Protection of Research Risks of the National Institute of Health.) In practice, the enclosed Affidavits of Dr. Stan E. Weed and Dr. Adrian P. Van Mondfrans provide specific and direct documentation both in terms of working with Federal studies over many years with at-risk youth, all levels of government, and university research that (1) full disclosure has been routinely made to parents, (2) written consents have been obtained, (3) there has been no need for extensive follow-up by researchers, and (4) rarely has any research been eliminated because of failure to appropriately design a study to meet consent criteria. I do not disagree that a higher rejection rate could be expected if studies were adequately disclosed to parents that were invasive of personal or family pri-

vacy, demeaned family members, asked questions inappropriate for an age level, or asked questions explicitly detailing sexual activity. (*See* Affidavit of Stan E. Weed, Ph.D., page 2, ¶ 8.)

There are at least two solutions to the presumed rejection rates in the question. First, the study can be redesigned to more appropriately match the values and beliefs of the parents and families involved in the study. Second, and more basic, those supporting both the research and funding efforts need to remember that ultimately the challenges posed to society at large arising will be resolved because of choices made on an individual and family basis and not because of expenditure of Federal funds and completion of more studies. Looking at widespread drug use problems, former Utah United States Attorney Brent Ward has reviewed the societal effect of individual choices, choices that ultimately government cannot cope with: "Turning for an illustration to the abuse of drugs, . . . data suggests that drug users possess limited resources to cope with psychological stress; that they take drugs to fill a moral and spiritual void and to meet these intense emotional needs. . . . Missing parents and throwaway children: government cannot clean up this mess. This is an abdication of sovereignty at the expense of future generations. . . . 'Freedom cannot live after the family as we know it is dead.'"[1] As the ultimate solutions are to occur on an individual and family level, why side-step parents and the family in the process of defining the nature of the problems and self-labeling those involved in the process? Indeed, for some federally funded studies, parental involvement was a key part of improving the validity of the study and working towards viable solutions. (See *Affidavit* of Stan E. Weed, Ph.D., page 2, ¶ 10.)

Question 3. Federal surveys currently protect the anonymity of survey responses. Do you have any specific examples of that anonymity being violated?

Speaking from my experience in education-related testing, a question of anonymity does not adequately address the fundamental issues at hand. Current Federal regulations in education specifically exempt from their "Protection of Human Subjects" regulations "research conducted in established or commonly accepted educational settings, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods." 34 C.F.R. Subtitle A § 97.101 (b)(1) (7–1–95). The invasive "self-esteem" testing used in the Chapter I setting described in my previous testimony could arguably have come under these regulations, and therefore been exempt. (However, this exemption would appear to be is in directly conflict with the current provisions of 20 U.S.C. § 1232h noted earlier, and could, therefore, be an unlawful exercise of agency power.) In the Utah litigation, those test results on the face were not anonymous to anyone directly involved in the teaching of the Plaintiffs' children.

More basic, however, is the concern raised in the affidavit of Dr. William Rodney Coulson that is also enclosed. (The affidavit had been submitted with the Federal litigation reported earlier.) He explains three key ideas: First, the tests were psychological tests and, in the traditional sense were not directly related to academic instruction relevant to Chapter I or the second or third grade (the grades of children receiving the tests.) (Affidavit of William Rodney Coulson, page 2, ¶ 5.) Second, the very nature of the disclosure required by the testing process encouraged "self-labeling" by the child regarding himself and his family. (*Id.* at 3, ¶ 7.) Third, the use of the test itself was "an effort, not directly related to academic use, that was designed to affect the behavior, emotional or attitudinal characteristics" of the children involved. (*Id.* at 3, ¶ 8.) In this instance (and many others) the issue is not only anonymity; the issue is a specific and direct effort to change the character and attitudes of children through a "self-labeling" process. The evidence submitted regarding the Utah litigation is specific and clear evidence with which I have been personally involved in which there was no anonymity on a local level and there were efforts made (from the parent's viewpoint) to have a child engage in a "self-labeling" process damaging to them and destructive of the values and beliefs of that family. Extensive testimony and evidence of these kinds of violations were documented in hearings held before the administrative rules were adopted for 20 U.S.C. § 1232h (see Phyllis Schlafly, ed., *Child Abuse in the Classroom,* containing testimony presented March 13, 16, 19, 20, 21, 23, 27, 1984) as well as that placed in the Congressional Record by Senator Grassley when amendments to the statute were presented and debated in the Senate on March 4, 1994.

As I have prepared these responses and reviewed my earlier written and oral testimony, I have also concluded that the language in H.R. 1271 creating a private

---

[1] Brent Ward, "Abdication of Popular Sovereignty in America," 11 Utah Bar Journal 29, 34–35 (1983).

right of action (page 4, lines 6–7) should more appropriately clarified by replacing the present language with two different sections, numbered as deemed appropriate:

Claim or Defense

Any parent or legal guardian a child, or any child after reaching age of majority as allowed by State law where the cause of action, claim or defense arose, may raise a violation of this Act in an action in a Federal or State court, or before an administrative tribunal of appropriate jurisdiction, as a claim or a defense.

Attorney's Fees

Subsections (b) and (c) of section 722 of the Revised Statutes (42 U.S.C. 1988 (b) and (c)) (concerning the award of attorney's and expert fees) shall apply to cases brought or defended under this Act. A person who uses this Act to defend against litigation or administrative action shall be construed to be the plaintiff for the purposes of the application of such subsections.

Thank you for the opportunity of responding to the follow-up questions and submitting clarifying language regarding a private right of action. If I can be of any additional assistance, feel free to contact me at your earliest convenience.

Sincerely yours,

MATTHEW HILTON

Enclosures: Affidavit of Stan E. Weed, Ph.D.
Affidavit of Adrian P. Van Mondfrans, Ph.D.
Affidavit of William Rodney Coulson

AFFIDAVIT OF STAN E. WEED, PH.D.

COMES NOW Stan E. Weed, Ph.D., under oath and penalty of perjury, and based upon his personal knowledge swears that the following is true:

1. That I am over eighteen years of age, of sound mind and body.

2. That I received a Ph.D. in 1978 from the University of Washington in the field of social psychology, a M.S. from Brigham Young University in 1972 in the field of psychology, and a B.S. from Brigham Young University in 1968 in the field of psychology.

3. That over many years, I have served in various professional capacities in the area of psychology, including that of researcher, research administration, counselor (family and adolescent), and graduate and undergraduate course instructor.

4. That since completing my doctoral work in social psychology, I have written or given 35 professional publications or addresses that have been specifically or indirectly focused on issues in psychology. My most recent research has focused on social problems and programs related to adolescents: teen pregnancy, drug abuse, and delinquency.

5. That because of this work with at-risk adolescent issues, I have served as a consultant to the United State Senate Committee on Labor and Human Resources, served on the national advisory board for Adolescent Family Life programs through the Federal Department of Health and Human Services, and served as an expert witness to the United States House Committee on Health and Transportation.

6. That from 1988 through 1994 I have been involved as a researcher fulfilling Federal contracts (using Title XX funding) which focused on studying problems associated with teenage pregnancy. I have studied the attitudes and conduct of over 35,000 at risk youth in many states, including Washington, Utah, Idaho, California, Illinois, Michigan, Wisconsin, Virginia, Missouri, and Mississippi.

7. That all of these research projects relating to at-risk adolescents required parental consent to meet Federal guidelines under Title XX legislation which we complied with.

8. That when a written consent was not received to proceed with testing an at-risk child, the child was excused from testing. Because of concerted efforts to not be invasive of personal or family privacy, demean other family members, ask questions inappropriate for an age level, or ask questions explicitly detailing sexual activity, it was an extremely rare event when a parent did not give permission once they understood the purpose content of the testing. However, in the event that a study did not follow these contract and regulatory guidelines regarding the nature of questions, a higher parental rejection rate could be expected.

9. That in studies I have been associated with, the extra-costs associated with securing written parental consent in these tests have not been significant or burdensome.

10. That, in my professional opinion, the securing of the written consent encouraged parental involvement and interaction with their child on these sensitive topics,

all of which eventually contributed to both a more accurate study and one in which there was increased family involvement focusing on the actual problems at issue.

11. That in none of the studies was the ultimate response rate significantly lower or negatively impacted because of the requirement that written parental consent be obtained after full disclosure was made to the parents of the nature of the testing that was to be done with their child.

DATE: November 30, 1995.

Stan E. Weed, Ph.D. [Signed]

County of Salt Lake)
:
State of Utah)

On the 30th day of November 1995, Stan E. Weed personally appeared before me and swore under oath and penalty of perjury that he had signed the foregoing affidavit and that the statements contained therein were true.

Dated this 30th day of November, 1995.

My Commission Expires: 2/21/96
Lora V. Kearns
NOTARY PUBLIC
Residing in: Salt Lake County

AFFIDAVIT OF ADRIAN P. VAN MONDFRANS, PH.D.

COMES NOW Adrian P. Van Mondfrans, Ph.D., under oath and penalty of perjury, and based upon his personal knowledge swears that the following is true:

1. That I am over eighteen years of age, of sound mind and body.

2. That I received a Ph.D. in 1978 from the University of Wisconsin in 1967, in the field of educational psychology, a M.A. from the University of Utah in 1964, in the field of educational psychology, and a B.S. from University of Utah in 1963, in the field of psychology.

3. That over many years, I have served in various professional capacities in the area of educational psychology, including that of researcher, research administration, assistant and associate dean of the College of Education at Brigham Young University and as professor at Purdue University, John Hopkins University, and Brigham Young University. I am presently a member of the Brigham Young University's Institutional Review Board ("IRB").

4. That since completing my doctoral work in educational psychology, I have published 22 professional publications, directed or been involved in at least 91 professional evaluation studies, and have presented over 64 other presentations to professional peers that use research skills relevant to educational psychology and social science testing procedures.

5. That my experience of performing research in a university setting (both for public and private interests) has always been that the institutional protocol with which I have been affiliated has required that written consent from parents (after full and complete disclosure) be obtained before any minor was examined or tested in any way. Disclosure forms are required by Brigham Young University, the Utah State Office of Education, and other agencies for which I completed research and evaluation projects.

6. That in all of my professional experience, I have understood and taught that to proceed without obtained written parental permission (and full and complete disclosure) would violate the ethical requirements of the Office for the Protection from Research Risks of the National Institute of Health as defined in their 1993 document "Protecting Human Research Subjects: Institutional Review Board Hand Book."

7. That when the Brigham Young University IRB has reviewed research proposals we have required that when a written consent from a parent was not received to proceed with testing an at-risk child, the child was excused from testing.

8. That in studies I have been associated with and those reviewed by the IRB, the extra-costs associated with securing written parental consent in these tests have not been significant or burdensome.

9. That it appears to be the case that in none of the studies done by me or reviewed by the IRB was the ultimate response rate significantly lower or negatively impacted because of the requirement that written parental consent be obtained after fill disclosure was made to the parents of the nature of the testing that was to be done with their child.

10. That this requirement of written parental consent did not lead to researchers abandoning their original research plan except in a very few cases where they could not justify the possible risks to human subjects of their proposed treatment or measurement plans.

DATE: November 30, 1995.

Adrian P. Van Mondfrans, Ph.D. [Signed]

County of Salt Lake
State of Utah

On the 30th day of November 1995, Adrian P. Van Mondfrans personally appeared before me and swore under oath and penalty of perjury that he had signed the foregoing affidavit and that the statements contained therein were true.
Dated this 30th day of November, 1995.

My Commission Expires: 1 November 1995
Karen C. Eddington
NOTARY PUBLIC
Residing in: Salt Lake County

AFFIDAVIT OF WILLIAM RODNEY COULSON

COMES NOW William Rodney Coulson, under oath and penalty of perjury, and based upon his personal knowledge swears that the following is true:

1. That I am over eighteen years of age, of sound mind and body.

2. That I am a licensed psychologist in the State of California.

3. That I hold degrees from the following Universities: Ph.D., University of Notre Dame, Philosophy (1964); Ed.D., University of California Berkeley (1965), Counseling Psychology; M.A., University of Notre Dame (1960), Philosophy; B.A., Arizona State University, English, Speech (1955).

4. That over many years, I have served in various professional capacities in the area of Psychology, including Professor of Psychology and Education and Director, Graduate Program in General Psychology, United States International University, San Diego, California (1981–1989), as a consultant with Federal Bureau of Prisons (1989–1990), U.S. Department of Education (1987–1988; 1990), U.S. Department of Justice (1990–present), and Research Associate, Western Behavioral Science Institute, (1965–68). Since completing my doctoral work in 1964, I have written or given 77 professional publications or addresses that have been specifically or indirectly focused on issues in psychology.

5. That I have reviewed in detail the nature of the actual Piers-Harris Children's Self-Concept Scale administered to the minor children in the above entitled case. It is my professional opinion that these documents are, in fact, psychological tests and that, in the traditional sense, are not directly related to academic instruction relevant to Chapter I or the second and third grade.

6. That my knowledge of psychological assessment techniques leads me to believe that the overwhelming weight of professional authority would support my observation that the Piers-Harris Children's Self-Concept Scale is, in fact, a psychological test.

7. Based on my experience as a clinical and counseling psychologist, I believe that requiring an elementary student to affirm or deny the statements made in the Piers-Harris test will elicit a response which will most likely disclose information and encourage self-labeling by the child regarding the following categories or topics indicated by the following groups of statements on the test:

a. Mental and psychological problems potentially embarrassing to the student or his family (Statement No.'s 74, 78.)

b. Sex Behavior and Attitudes: (Statement No.'s: 29, 54, 57, 69, 73.)

c. Anti-social, self-incriminating or demeaning behavior: (Statement No.'s: 2, 3, 4, 6, 7, 8, 10, 11, 13, 14, 18, 20, 22, 25, 26, 27, 31, 32, 34, 40, 43, 45, 46, 47, 48, 50, 53, 56, 58, 59, 61, 64, 68, 71, 72, 74, 75, 78, 79.)

d. Critical appraisals of other individuals with whom the respondents have a close family relationship: (Statement No.'s: 38, 59, 62.)

8. That because of the self-labeling reviewed in paragraph 7, were the test to be used as a pre-test and post-test in an effort to monitor change of attitude among students or performance of counselors and teachers, I believe the use of the test itself would be an effort, not directly related to academic use, that was designed to affect the behavior, emotional or attitudinal characteristics of an individual or group.

FURTHER YOUR AFFIANT SAITH NOT.
Dated November 23, 1994.

William Rodney Coulson [Signed]

County of Mendocino
State of California

On the 30th day of November 1994, William Rodney Coulson personally appeared before me and swore under oath and penalty of perjury that he had signed the foregoing affidavit and that the statements contained therein were true.

Dated this 30th day of November, 1994.

My Commission Expires: 1–21–98
Nancy R. Cox
NOTARY PUBLIC
Residing in: Fort Bragg, California

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

DEC 1 1995

Honorable Ted Stevens
Chairman
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for the opportunity to testify and provide additional written information to the Committee on H.R. 1271, the Family Privacy Protection Act. As requested through the questions from yourself and Senators Glenn and Levin, we have attempted to demonstrate the careful and extensive protections that are presently in place to safeguard the privacy of children and families.

We share your desire to promote and support the rights of parents to be involved in the activities of their children. To that end, we are providing alternative legislative language to the written consent requirement. We believe this language advances the rights and involvement of parents, while preserving the government's ability to conduct valuable research on the high risk practices of our youth today.

As always, we would be happy to provide additional assistance or information upon your request.

Sincerely,

Sally Katzen

Sally Katzen

Enclosures

QUESTIONS BY SENATOR STEVENS

1. **Please explain the role of OIRA in reviewing surveys or questionnaires that are fully or partially funded by the federal government? Does OIRA review all surveys or questionnaires funded by federal grants?**

The Paperwork Reduction Act (PRA) of 1995 charges the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) with responsibility for the review of Federal information collections. OMB reviews agency information collections to minimize the paperwork burden for individuals, and improve the quality and use of the information, as well as to protect the rights and privacy of individuals providing the information. Under the Act, an information collection takes place when an agency obtains, causes to be obtained, solicits or requires the disclosure of either: 1)answers to identical questions of ten or more persons; or, 2)answers to questions posed to agencies, instrumentalities or employees of the U.S. for general statistical purposes. Thus, OIRA reviews all surveys or questionnaires that meet the definition of information collections; which includes most Federally sponsored research.

Under the PRA, OMB has authority to review surveys and questionnaires funded by federal grants when: 1) the recipient of a grant is conducting the collection of information at the specific request of the agency; or 2) the terms and conditions of the grant require specific approval by the agency of the collection of information or collection procedures.

2. **The Department of Health and Human Services (HHS) regulations (45 CFR Part 46- Protection of human subjects) have been cited as currently providing protections for minors participating in surveys and questionnaires. What was the genesis of these regulations? Were they written with the surveys and questionnaires on privacy topics as listed H.R. 1271 in mind?**

In 1974, the Congress passed the National Research Act (P.L. 93-348), which directed the Secretary of Health, Education and Welfare (HEW) (HHS today) to require "by regulation" that each entity applying for a federal grant, contract, or cooperative agreement to conduct biomedical or behavioral research involving human subjects have an Institutional Review Board (IRB) that reviews and approves all human subject research proposals conducted at, or supported by, that entity "to protect the rights of the humans subjects of such research." The 1974 Act also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was directed to develop recommendations, for promulgation into regulation by the Secretary of HEW.

The National Commission met between 1974 and 1979 and issued a series of reports and recommendations that were the basis for the Federal Regulations for the Protection of Human

Subjects of Research (45 CFR 46). The National Commission deliberated extensively on behavioral research using surveys and questionnaires, including issues of privacy and parental consent, such as those listed in HR 1271, which were incorporated into the Federal Regulations. Moreover, in 1977, the National Commission issued a special report and recommendation regarding research involving children. Following an exhaustive public comment period, the Department promulgated final rules in 1981 to create 45 CFR 46, subparts A-D.

3. **Please provide the Committee with copies of surveys or questionnaires in each category of research approved under 45 CFR part 46 that solicit information from minors on the privacy topics listed in H.R. 1271, noting the degree of consent required by the Institutional Review Board and the category of research the survey falls under: 1)not involving greater than minimal risk; 2)involving greater than minimal risk, but presenting the prospect of direct benefit to the individual; 3)involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition; 4)not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.**

Attached are copies of three surveys that fall under category one. The other categories listed above apply to biomedical research (as opposed to behavioral) which is not covered under the PRA, and generally does not use survey or questionnaire instruments. As such, OMB does not have any examples of research under these categories.

For the attached surveys, we have also included a brief description of the research effort, a copy of the consent form, and the agency response to justify the inclusion of any sensitive questions:

1. The Community Partnership Demonstration Program Survey: Student Survey and Adult Community Survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA). The survey utilizes a consent form, sent home to the parent.

2. Evaluation of Job Corps Drug Treatment Enrichment Program, conducted by SAMHSA. The survey includes multiple levels of parental consent including written, passive, and oral, depending upon State law.

3. Evaluation of the Comprehensive Mental Health Services Program for Children, conducted by the Center for Mental Health Services within SAMHSA. The survey includes a written consent form.

4.**What enforcement measures exist to guarantee compliance with the HHS regulations (CFR Part 46)?**

If an individual researcher or institution is found to have violated the provisions of the Federal Regulation for the Protection of Human Subjects of Research, the Secretary of HHS has the authority to:

a. Withdraw, by suspension or termination, current funding for the research, and

b. Bar the individual and/or institution from future federal research funding for a period of time to be determined (to date, the longest period of disbarment that has been imposed is for a period of ten years).

5. **You recommend allowing alternatives to the requirement for "written" consent, and stated that a bill could be crafted to strengthen parental consent without the written consent requirement. Do you have an alternative legislative proposal?**

Add to page three of H.R. 1271, under Section two after line 15:

(d) An Institutional Review Board, established under the common Federal Policy for the Protection of Human Subjects of Research or an equivalent entity at the local level, may provide for an alternative mechanism to solicit parental consent:

> (1) if the research poses minimal risk of harm to the minor, and a written parental consent requirement would jeopardize the research. Any such alternative must ensure that the parent is informed in advance of the research activities and must be provided with a simple opportunity to respond, such as a postage paid envelope or 800 number; or
>
> (2) if the written consent is not a feasible or reasonable requirement, as in the case where the child is institutionalized, in custody of the State, a runaway, homeless, abused and or neglected.

6. **You referenced runaways, homeless and abused children as examples for which written parental consent would be virtually impossible. Do you have a specific suggestion for a limited exemption to address the categories where there is no parent or guardian?**

See above subsection (2)

QUESTIONS BY SENATOR GLENN

1. **Please provide for the record a copy of current regulations governing privacy protections and parental consent for federally-supported research. Please summarize those rules and procedures, particularly with regards to research involving minors.**

The Department of Health and Human Service regulations under 45 CFR 46 (copy attached) govern Federally sponsored human subjects research. Sixteen agencies responsible for the majority of Federal research conducted have also adopted the Human Subjects regulations under the "Common Rule." The Human Subjects regulations are designed to assure that research

subjects are informed of any risks and benefits of proposed research, and that they are given sufficient information about the research to decide whether to participate.

HHS specifically addresses the involvement of parents or guardians in their research with children under subpart D of 45 CFR 46. The regulations require that any proposed research projected conducted by Federal grantees be reviewed and approved by an official Institutional Review Board (IRB) whose deliberation must consider such issues as consent, privacy, confidentiality, benefits, and risks. IRB's, made up of local members from academia and research institutions and community representatives, such as parents and teachers, review proposed research to protect the rights of participants. IRB's specifically review the parental consent standard and the procedures in place to assure confidentiality and anonymity of respondents.

The rules in Section 45 CFR 46.117 that apply to all research require that informed consent be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. The IRB may only waive the written consent requirement: 1) when the consent form is the only document linking the individual with the research conducted and this would present a potential risk to the individual; or, 2)when the research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context.

2. **What is the relation of Federal guidelines to State or local laws or rules affecting research? To what extent are States or local communities free to regulate the conduct of research involving minors?**

The Federal Regulation for the Protection of Human Subjects apply to all federally funded research involving human subjects. All federally funded researchers and their sponsoring institutions must comply with the Federal Regulations, as well as be in compliance with State and local laws. States and local communities are free to add any additional requirements to regulate the conduct of all research, including that which involves minors that is conducted within their jurisdiction. The States and local communities, however, may not negate the requirements in the Federal Regulations.

3. **How do you use the Paperwork Reduction Act's clearance process to review the nature and substance of surveys and other Federally supported research, particularly with regards to the personal sensitivity of research topics?**

OIRA reviews all Federal information collections to ensure that they are necessary for the proper performance of the functions of the agency. Each Agency submitting an information collection for review under the PRA must complete an OMB form, (OMB 83-I) that requires the agency to:

> "*Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons*

why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested and any steps to be taken to obtain their consent."

As part of this process, we may identify and recommend removal of questions that are inappropriate, overly intrusive or are cannot be justified in relation to the agency's mission. We may also seek to strengthen the parental consent policy proposed in a given survey if we think it does not afford sufficient protections and privacy safeguards to the child and family. For example, at our recommendation, HHS strengthened an informed consent requirement to a recent Public Health Service survey related to drug interventions.

4. **Please compare the scope and impact of H.R. 1271 with Senator Grassley's 1994 Education Goals 2000 Amendment.**

H.R. 1271 imposes an across-the-board written parental consent requirement for surveys and questionnaires conducted under *all* programs or activities funded in whole or in part by the Federal Government. This bill dramatically expands the scope of the Grassley Amendment which currently applies only to those surveys, analyses, or evaluations conducted under Department of Education (DoEd) programs.

H.R. 1271 mirrors much of the language of the Grassley amendment, although a number of important differences exist -- the impact of which would create two separate standards; one for Education and another for all other programs. The application of differing standards, depending on the source of funding for a particular survey or questionnaire, is likely to cause significant confusion and administrative burdens at the local school or community level. Even the most well-intentioned parents will find it difficult to keep up with their respective rights under the different standards.

The Administration continues to oppose any across-the-board written parental consent requirement. If however, Congress were to adopt specific standards for all other agencies, the Administration recommends that a uniform approach be applied to all programs.

QUESTIONS BY SENATOR LEVIN

1. Current regulation (45 CFR 46 Subpart A) adopted by 17 federal agencies that conduct the vast majority of federally funded research on children require written parental consent for surveys of children, unless an agency's Institutional Review Board decides, on a case-by-case basis, that the research poses "minimal risk of harm" to the child or would impair confidentiality and issues a waiver.

A. Would this bill eliminate any possibility of a waiver?

As presently written, the bill would establish an across-the-board requirement of written consent for any Federally sponsored survey or questionnaire involving questions in the areas specified in the bill. While the bill provides exceptions to the written consent requirement, it does *not* allow for a waiver or provide any other discretionary authority to sponsoring agency, IRB's or researcher in the field.

B. Would the bill be improved if it made use of this existing procedure and provided added standards for granting a waiver in surveys directed to children?

The bill would be dramatically improved if it required all Federal agencies to adhere to 45 CFR 46 and provided for flexibility to the IRB in specified circumstances. This would establish written consent as the standard policy for Federal research, but maintain sufficient flexibility in specified circumstances. We have provided draft language that would implement this approach, in response to Senator Stevens' question number five.

2. **If a questionnaire is developed by a single teacher for a single class, in a school that receives federal funding, and given without written parental consent, would this constitute a violation of H.R. 1271?**

The answer to this question is subject to interpretation. If the term "program or activity" in H.R. 1271 is construed in the same way as it has been defined under the Civil Rights Restoration Act of 1988, H.R. 1271 requirements would be extended to include research undertaken by any entity that receives Federal funding, including States, cities, universities, and even schools. Thus if the questionnaire developed by a single teacher, for a single class in a school that received Federal funding contained any 'sensitive questions", it would, under this interpretation, be covered by H.R. 1271.

Such a far-reaching interpretation poses a number of problems. In an era of devolution of decision-making authority to the State and local levels, this interpretation would seem to contradict the philosophy of maximizing grantee flexibility. In addition, it raises possible questions of unfunded mandates. Written consent requirements can be costly. The Congressional Budget Office cites a Rand Corporation study that maintains that the written consent requirement could increase the cost of acquiring consent (not the cost of the whole study) by more than 15 fold, in order to maintain the necessary response rates.

The Administration believes the legislation should be amended to avoid the possibility of such an overbroad interpretation. We recommend replacing "program or activity" on line 4 of page two of H.R. 1271 with "survey or questionnaire." This change will limit the scope of the bill and make it clear that the bill is intended to focus on federally funded surveys.

(e) The employee may, thereafter, request either (1) indemnification to satisfy a verdict, judgment or award entered against the employee or (2) payment to satisfy the requirements of a settlement proposal. The employee shall submit a written request, with documentation including copies of the verdict, judgment, award or settlement proposal, as appropriate, to the head of his employing component, who shall thereupon submit to the General Counsel, in a timely manner, a recommended disposition of the request. The General Counsel shall also seek the views of the Department of Justice. The General Counsel shall forward the request, the employing component's recommendation and the General Counsel's recommendation to the Secretary for decision.

(f) Any payment under this section either to indemnify a Department of Health and Human Services employee or to settle a personal damage claim shall be contingent upon the availability of appropriated funds of the employing component of the Department of Health and Human Services.

AUTHORITY: 5 U.S.C. 301.

[53 FR 11280, Apr. 6, 1988]

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Sec.
46.101 To what does this policy apply?
46.102 Definitions.
46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
46.104–46.106 [Reserved]
46.107 IRB Membership
46.108 IRB functions and operations.
46.109 IRB review of research.
46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
46.111 Criteria for IRB approval of research.
46.112 Review by institution.
46.113 Suspension or termination of IRB approval of research.
46.114 Cooperative research.
46.115 IRB records.
46.116 General requirements for informed consent.
46.117 Documentation of informed consent.
46.118 Applications and proposals lacking definite plans for involvement of human subjects.
46.119 Research undertaken without the intention of involving human subjects.
46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
46.121 [Reserved]
46.122 Use of Federal funds.
46.123 Early termination of research support: Evaluation of applications and proposals.
46.124 Conditions.

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

46.201 Applicability.
46.202 Purpose.
46.203 Definitions
46.204 Ethical Advisory Boards.
46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.
46.206 General limitations.
46.207 Activities directed toward pregnant women as subjects.
46.208 Activities directed toward fetuses in utero as subjects.
46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.
46.210 Activities involving the dead fetus, fetal material, or the placenta.
46.211 Modification or waiver of specific requirements.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

46.301 Applicability.
46.302 Purpose.
46.303 Definitions.
46.304 Composition of Institutional Review Boards where prisoners are involved.
46.305 Additional duties of the Institutional Review Boards where prisoners are involved.
46.306 Permitted research involving prisoners.

Subpart D—Additional Protections for Children Involved as Subjects in Research

46.401 To what do these regulations apply?
46.402 Definitions.
46.403 IRB duties.
46.404 Research not involving greater than minimal risk.
46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
46.408 Requirements for permission by parents or guardians and for assent by children.
46.409 Wards.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289.

EDITORIAL NOTE: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost—sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be

maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, Department of Health and Human Services (HHS), and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.[1]

[1] Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well.

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991]

§ 46.102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been

However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

reviewed and approved by an IRB in accordance with an approved assurance.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, HHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under § 46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with § 46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under § 46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by § 46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by § 46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under control number 9999–0020)

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991]

§§ 46.104—46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(o) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in §46.103(b)(4) and, to the extent required by, §46.103(b)(5).

(b) Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under control number 9999-0020)

§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator.

appropriate institutional officials, and the department or agency head.

(Approved by the Office of Management and Budget under control number 9999–0020)

§ 46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § 46.103(b)(4) and § 46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under control number 9999–0020)

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under control number 9999–0020)

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under control number 9999–0020)

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 [Reserved]

§ 46.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragarph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in Vitro Fertilization

SOURCE: 40 FR 33528, Aug 8, 1975, unless otherwise noted.

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human in vitro fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

count a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research

SOURCE: 48 FR 9818, Mar. 8, 1983, unless otherwise noted.

§ 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to

this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

[48 FR 9818, Mar. 8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991]

§ 46.402 Definitions.

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for

the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of § 46.404, § 46.405, or § 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) That the research in fact satisfies the conditions of § 46.404, § 46.405, or § 46.406, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 46.404 or § 46.405. Where research is covered by §§ 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under § 46.406 or § 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

PART 50—U.S. EXCHANGE VISITOR PROGRAM—REQUEST FOR WAIVER OF THE TWO-YEAR FOREIGN RESIDENCE REQUIREMENT

Sec.

50.1 Authority.
50.2 Exchange Visitor Waiver Review Board.
50.3 Policy.
50.4 Procedures for submission of application to HHS.
50.5 Personal hardship, persecution and visa extension considerations.
50.6 Release from foreign government.

AUTHORITY: 75 Stat. 527 (22 U.S.C. 2451 et seq.); 84 Stat. 116 (8 U.S.C. 1182(e)).

SOURCE: 49 FR 9900, Mar. 16, 1984, unless otherwise noted.

§ 50.1 Authority.

Under the authority of Mutual Educational and Cultural Exchange Act of 1961 (75 Stat. 527) and the Immigration and Nationality Act as amended (84 Stat. 116), the Department of Health and Human Services is an "interested United States Government agency" with the authority to request the United States Information Agency to recommend to the Attorney General waiver of the two-year foreign residence requirement for exchange visitors under the Mutual Educational and Cultural Exchange Program.

§ 50.2 Exchange Visitor Waiver Review Board.

(a) *Establishment.* The Exchange Visitor Waiver Review Board is established to carry out the Department's responsibilities under the Exchange Visitor Program.

(b) *Functions.* The Exchange Visitor Waiver Review Board is responsible for making thorough and equitable evaluations of applications submitted by institutions, acting on behalf of exchange visitors, to the Department of HHS for a favorable recommendation to the United States Information Agency that the two-year foreign residence requirement for exchange visitors under the Exchanges Visitor Program be waived.

(c) *Membership.* The Exchange Visitor Waiver Review Board consists of no fewer than three members and two alternates, of whom no fewer than three shall consider any particular application. The Director of the Office of International Affairs, Office of the Secretary, is an ex officio member of the Board and serves as its Chairman. The Director may designate a staff member of the Office of the Secretary to serve as member and Chairman of the Board in the Director's absence. Two regularly assigned members and two alternates are appointed by the Assistant Secretary of Health to consider applications concerning health, biomedical

REQUEST FOR OMB APPROVAL

Community Partnership Demonstration Program Surveys: Student Survey and Adult Community Survey

(Excerpts from the survey - pages 2, 3, 9, and 31)

December 1992

PART A: JUSTIFICATION

1. Circumstances that Make the Collection of Information Necessary

The Community Partnership Demonstration Program, operated by the Center for Substance Abuse Prevention (CSAP), has as its goal to promote the development of long-range, comprehensive, multi-disciplinary alcohol and drug abuse prevention planning and programs. This goal will be reached through the formation and support of community partnerships involving coalitions of public and private organizations. Each Partnership will plan and coordinate activities to enhance, promote, and improve effective prevention program implementation at its local level. This planning and coordinating work usually occurs during regularly scheduled meetings of the Partnerships' members as a full coalition or in committees. The Partnerships strive to create an AOD prevention plan for their community and then sponsor or carry out activities toward that plan, such as youth activities and workplace campaigns. Partnerships range in size from less than 10 to over 200 people representing about as many organizations. (See Appendix A for the Program Announcement.)

The Community Partnership Demonstration Program provides assistance to 251 communities for the prevention of substance abuse through five-year grants totaling $500 million from the Center for Substance Abuse Prevention. The grants for these 251 programs were awarded in two rounds of funding -- 95 in the fall of 1990 and 156 in the fall of 1991. No further awards are planned. The awards average $325,000 per year and vary in size from $70,000 per year for five years to over one million dollars per year at individual sites. The sites vary widely, from small rural areas to major cities, with some targeting specific groups, such as youth, minorities, or neighborhoods, while others target the general population of their entire geographic area.

Public Law 100-690 authorizes CSAP to do studies of alcohol and drug prevention programs. The specific focus of this project is to evaluate the effectiveness of the five-year Community Partnership Demonstration Program, authorized under P.L. 100-690 (revised November 18, 1988); section 508b(2) and (7) and; section 508b amendment 10(B) "evaluate the success of different community approaches toward the prevention of substance abuse" (see Appendix B for a copy of relevant legislation).

Our nation is currently faced with an epidemic of alcohol and drug use of dire proportions. A central premise underlying the structure and goals of Community Partnership Demonstration Program is that prevention falls under the purview of myriad groups, including parents, schools, public health and welfare agencies, law enforcement, media groups, community organizations, and the business community. Furthermore, the Community Partnership Demonstration Program is based on the belief that the best way to prevent abuse is through coordinated, systematic efforts of key agencies, organizations, and individuals. Thus, the main element of each program funded is a Partnership that includes relevant agencies and organizations. Each Partnership develops specific prevention activities

targeting both youth and adults to serve the Partnership's particular needs and fit their resources. It is the effect of these Partnerships and their chosen activities on alcohol and drug abuse that is the main interest of this study and the instruments we are proposing to use.

Clearance is being sought for two uniform survey instruments (one for youth, the other for adults) needed to assess the effects of Community Partnership Demonstration Program partnerships on alcohol and drug abuse in various locations, with data collection to begin in April 1993. CSAP has contracted with ISA Associates to administer the surveys of alcohol and drug use (and related perceptions and attitudes) in 48 sites, 24 program sites and 24 non-program comparison communities matched on several variables. The 24 program sites will be selected from among the 36 representative communities randomly selected for current intensive study from among the 251 communities that received grants. This is the second year of the Partnership Program and we have visited 25 of these 36 programs; some have been visited twice and growth has been observed over a year interval. The remaining 11 sites will be visited for the first time in early 1993. Impact study sites will be selected for representativeness from among those sites with a functioning, viable Partnership. The 24 comparison communities will be matched on as many variables, such as population density and socioeconomic status, as possible from communities that do not have partnerships. Using comparison communities will allow the study to determine if the program caused a measurable difference on self-reported alcohol and drug use above what is measured in an area without a program. By collecting uniform alcohol and drug abuse survey data at three points in time (pre- and post-intervention, and midpoint as well) at all 48 locations, we will be able to assess and compare changes in alcohol and drug use rates at both Partnership and comparison locations.

Even though similar alcohol and drug surveys are intermittently administered at various locations around the United States, this separate data collection is required because: 1) comparable alcohol and drug use data are not available across the 48 study locations, 2) the study needs to assess alcohol and drug use at precise points in time--before and after the Partnership intervention, and 3) the study needs measures relevant to the specificity of the local target populations that can only be reached by targeted surveys.

2. How, by Whom, and for What Purpose the Information is to be Used

The proposed data collection will provide information on whether Partnerships result in a reduction in self-reported alcohol or drug use (and related perceptions and attitudes) in targeted areas. To accomplish this, the sampling plan will permit the study to calculate estimates of drug use among both youth and adults in the targeted areas, as well as comparison locations. The Community Partnership Demonstration Program is an innovative approach to America's alcohol and drug abuse crisis, and it is important that it be evaluated in this rigorous and precise fashion.

The information obtained in this study will be used by policy makers, planners, and analysts in the CSAP to develop program policies and guidelines to improve the

11. Questions of a Sensitive Nature

Because the Community Partnership Demonstration Program is an alcohol and other drug abuse prevention program, the proposed data collection surveys necessarily focus on respondents' alcohol and drug use behavior and attitudes. The surveys, therefore, do contain questions of a sensitive nature. These questions are necessary because CSAP is specifically interested in whether the programs they are funding affect alcohol and drug use behavior and attitudes among youth and adults. It is CSAP's mission, as outlined in Public Law 100-690, section 508b(2)(7)(10) -- see Appendix B. Most of the questions asked in this survey have been used successfully in previous questionnaires. To encourage full responses, a technique will be adopted from NIDA's Household Survey, wherein student respondents mark their responses to sensitive questions themselves, without the interviewer seeing the response.

The data collected will be used to assess the impact of the Community Partnership Demonstration Program on drug and alcohol use behavior and attitudes. Answers to specific questions will not be linked to specific respondents at all for adults, and, for youth, only ID numbers will be used on the surveys. Furthermore, as noted above, the results will only be reported in aggregate form.

12. Estimates of Annualized Cost

Cost to the Federal Government. The original total cost of the contract awarded for this study was $2.1 million, extending over 36 months. CSAP now plans to extend the contract by 4.5 years to conduct an impact evaluation. The costs of the conduct of these two surveys total to about $2.3 million per administration. The total amount of $6.9 million represents all direct and indirect costs to design the surveys, collect and process data, analyze the data, and prepare and disseminate reports, including a $10 incentive to be paid to each out-of-school youth (for the 12+2 cohort in wave 3), a prize at each site for youth worth $500, and a stipend of $1,000 per site for their participation.

The costs for the three waves of data collection are broken out as follows:

Baseline:	$2,064,176
Wave 2, two years after baseline:	$2,275,754
Wave 3, two years after Wave 2:	$2,653,019

The total cost of the administration of the two surveys over the three waves will be $6,992,949. Costs for Wave 2 and Wave 3 were based on a 5% increase per year for two years each wave. Wave 3 costs also include the $10 incentive for out of school students. The annualized cost over the five years of data collection would be $1,398,590.

Costs to the Respondents. Cost estimates were calculated by multiplying the number of respondent hours for each type of respondent times the number of respondents. The time estimates were based on a pilot test of the survey instruments in which both youth and adult respondents completed the surveys in 30 minutes or less. Allowing time for

Figure B-2: Letter to Parents

Notice to parents: [on CSAP or HHS letterhead, with an appropriate signator]

Your child has been selected to participate in a study conducted for the U.S. Department of Health and Human Services by a private research firm. The study will help the Federal Government assess the effectiveness of substance abuse prevention programs.

Your child will be asked to fill out a questionnaire on how he or she feels about cigarettes, alcohol and drugs. Two years from now and again four years from now, your child will be asked to fill out the questionnaire again.

Your child's responses to the questions will be confidential -- no one outside the rersearch firm conducting the study will see the responses. Your child's name will not appear on the questionnaire. In order to link each person's questionnaires over the three times the questionnaire is given, each person will be assigned an identification number; that number will be the only identification on the questionnaire. The list of ID numbers and names will be kept in a location separate from the questionnaire data, making it almost impossible for anyone to link your child's name with his or her responses without permission. The results from the questionnaires will be reported only in the form of totals and averages based on hundreds of respondents, so it will be impossible to tell how any individual child responded.

Because it is important that we get the most accurate information possible, special protections are provided to ensure your child's privacy. Your child's responses are protected by a Federal Certificate of Confidentiality. This Certificate will protect the investigators from being forced to release any research data in which your child is identified, even under a court order or subpoena. Your child's participation will not put him or her at any risk, and their truthful responses will be of great value.

Your child's participation in this study is voluntary. There are no penalties if your child does not want to take part or does not want to answer all the questions, or if you do not want your child to take part. Of course, your child's participation in this important study is greatly appreciated and will be extremely helpful in helping the Federal Government decide how effective its substance abuse prevention programs are. This study is authorized by Section 516 of the Public Health Service Act (42 USC 290bb-22)

If you do not want your child to participate in this study, check the box next to the statement below, and sign in the space provided. If you return this signed form to the school by *[date to be filled in]*, your child will be excused from participating in the survey. (If you consent to your child's participation, you do not need to return this form.)

[ ] I do not want my child to participate in the study described above.

Signed: _____ Date: _____

Thank you very much for your time and cooperation.

Sincerely,

Signator,
Office

APPENDIX D

Form Approved
OMB No. 0930-XXXX
Exp. Date_____

STUDENT SURVEY

This questionnaire is part of a nationwide study of how students feel about drugs and alcohol. The survey is being conducted by a private research firm for the federal government.

If the study is to be helpful, it is important that you answer each question as thoughtfully and frankly as possible. Remember that all your answers will be kept *confidential* -- no one in your school or community will ever know how you answered the questions. Furthermore, the survey is *anonymous* -- we do not want you to put your name anywhere on the questionnaire.

Because it is important that we get the most accurate information possible, special protections are provided to ensure your privacy. The confidentiality of your responses is protected by a Federal Certificate of Confidentiality. This Certificate will protect the investigators from being forced to release any research data in which you are identified, even under a court order or subpoena. Your parents or school will never see your answers; only the researchers connected with the study. Your participation will not put you at risk, and your truthful responses will be of great value.

The study is completely voluntary. There is no penalty if you choose not to fill out the questionnaire or any part of it. This study is authorized by Section 516 of the Public Health Service Act (42 USC 290bb-22)

Two years from now and again four years from now, you will be asked to fill out the questionnaire again.

We think you will find the questionnaire to be very interesting and that you will enjoy filling it out. Be sure to read the instructions on the next page before you begin to answer. Thank you very much for being an important part of this study.

Public reporting burden for this collection of information is estimated to average 30 minutes per response (40 minutes including the time for reviewing instructions). Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to PHS Reports Clearance Officer; ATTN: PRA; Hubert H. Humphrey Bg.Rm 721-B; 200 Independence Ave., SW; Washington, DC 20201, and to the Office of Management and Budget; Paperwork Reduction Project (0930-XXXX); Washington, DC 20503.

STUDENT SURVEY

Your ID number: _____

Your school: _____

Your classroom number: _____

Today's date: _____ What time is it? _____

INSTRUCTIONS

1. This is not a test, so there are no right or wrong answers. We would like you to work fairly quickly, so that you can finish.

2. You should answer each question by marking one of the answer boxes. If you don't find an answer that fits exactly, choose the one that comes closest. If any question does not apply to you, or if you are not sure what it means, just leave it blank.

3. Mark your answers carefully so we can tell which answer box you chose. **Do not mark more than one box for any question, and do not mark in between the boxes.**

   This mark will work: [X]
   [ ]

   This mark will NOT work: [ ]
   X
   [ ]

4. If you have any questions raise your hand and someone will come to help you.

5. When you are finished with the questionnaire raise your hand.

I. FACTS ABOUT YOU

1. What grade are you in now?

   1 [ ] 5th grade
   2 [ ] 6th grade
   3 [ ] 7th grade
   4 [ ] 8th grade
   5 [ ] 9th grade
   6 [ ] 10th grade
   7 [ ] 11th grade
   8 [ ] 12th grade
   9 [ ] not in school

2. Are you male or female?

   1 [ ] male
   2 [ ] female

3. What year were you born? _____

4 What category would you call yourself?

1 [ ] White, not of Hispanic origin
2 [ ] Black, not of Hispanic origin
3 [ ] Asian or Pacific Islander
4 [ ] Hispanic
5 [ ] American Indian or Alaskan Native
6 [ ] Other (write in)_____

5. What is your home zip code?_____

The next nine questions are about your attitudes and your friends' attitudes toward cigarettes, alcohol, and drugs.

6. Would drinking alcohol make you less shy?

1 [ ] Yes, most of the time
2 [ ] Yes, sometimes
3 [ ] Yes, but hardly ever
4 [ ] No, never

7. If you use alcohol or drugs, will you have more health problems than other people?

1 [ ] Yes
2 [ ] Probably
3 [ ] I don't think so
4 [ ] No

8. If I don't use alcohol or drugs I will be happier.

1 [ ] Strongly agree
2 [ ] Agree
3 [ ] Disagree
4 [ ] Strongly disagree

9. What would your best friends think if you got drunk once in a while?

1 [ ] They would be angry with me.
2 [ ] They would be a little upset.
3 [ ] They wouldn't care one way or the other.
4 [ ] They would accept me.
5 [ ] They would be glad.

10. Smoking cigarettes fits with the kind of life I want to lead.

1 [ ] Yes, definitely
2 [ ] Yes, probably
3 [ ] Probably not
4 [ ] Definitely not

11. How do you think your closest friends feel about this statement:
People who use drugs are stupid.

1 [ ] Strongly agree
2 [ ] Agree
3 [ ] Disagree
4 [ ] Strongly disagree

12. Getting drunk every now and then fits with the kind of life I want to lead.

1 [ ] Yes, definitely
2 [ ] Yes, probably
3 [ ] Probably not
4 [ ] Definitely not

13. Would using cocaine help you have more fun at parties?

1 [ ] Yes, definitely
2 [ ] Yes, probably
3 [ ] Probably not
4 [ ] Definitely not

14. How do you think your closest friends feel about this statement?
It is cool to get drunk.

1 [ ] Strongly agree
2 [ ] Agree
3 [ ] Disagree
4 [ ] Strongly disagree

II. CIGARETTES, ALCOHOL AND DRUGS

The next questions are about CIGARETTES. Remember, for each question check one box.

15. Have you EVER SMOKED a cigarette -- even just a few puffs?

1 [ ] Yes
2 [ ] No

16. On how many DAYS did you smoke a cigarette in the LAST MONTH (30 days)?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

17. How many times have you smoked a cigarette in the LAST YEAR?

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

18. On the days you smoke cigarettes, how many do you smoke?

1 [ ] Less than 1 cigarette
2 [ ] 1 or 2 cigarettes
3 [ ] 3 to 7 cigarettes
4 [ ] About half a pack of cigarettes
5 [ ] A pack or more of cigarettes
6 [ ] I don't smoke cigarettes

The next few questions are about ALCOHOL. By alcohol, we mean BEER, WINE, WINE COOLERS, GRAIN ALCOHOL or HARD LIQUOR. These questions refer to the use of alcohol for other than religious purposes.

19. How often are you with kids who are drinking alcohol?

1 [ ] Often
2 [ ] Sometimes
3 [ ] Hardly ever
4 [ ] Never

20. Do you think your best friend drinks alcohol sometimes?

1 [ ] Yes
2 [ ] No

21. If your friends found out that you drank alcohol sometimes, how do you think they'd feel?

1 [ ] They would approve
2 [ ] They would disapprove but still be my friends
3 [ ] They would disapprove and stop being my friends
4 [ ] They wouldn't care

22. How would your parents feel if they found out you drank alcohol sometimes?

1 [ ] Not at all upset
2 [ ] A little upset
3 [ ] Pretty upset
4 [ ] Very upset
5 [ ] They wouldn't care

23. Have you EVER had a drink of alcohol? (By a drink, we mean a can of beer, a glass of wine, a wine cooler, or a shot of hard liquor.)

1 [ ] Yes
2 [ ] No

24. Do you think you will drink alcohol in the next six months?

1 [ ] Definitely yes
2 [ ] Probably yes
3 [ ] Probably no
4 [ ] Definitely no

25. How many times have you been offered any alcohol in the past year?

1 [ ] Never
2 [ ] Once
3 [ ] Twice
4 [ ] 3 or 4 times
5 [ ] 5 times or more

26. Do you think you could buy alcohol if you wanted to?

1 [ ] Yes
2 [ ] No

27. On how many DAYS did you have an alcoholic drink in the LAST MONTH (30 days)? (By a drink, we mean a can of beer, a glass of wine, a wine cooler, or a shot of hard liquor.) For example, if you drank alcohol each weekend night, that would be 8 days (4 weekends times 2 days each weekend).

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

28. On how many DAYS have you had an alcoholic drink in the LAST YEAR?
(By a drink, we mean a can of beer, a glass of wine, a wine cooler, or a shot of hard liquor.) For example, if you drank alcohol each weekend night, that would be about 100 days (about 50 weekends times 2 days each weekend).

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

29. On how many DAYS in the LAST MONTH (30 days) did you have THREE OR MORE alcoholic drinks?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

30. On the days you drink alcohol, about how many drinks do you have? (By a drink, we mean a can of beer, a glass of wine, a wine cooler, or a shot of hard liquor.)

1 [ ] Less than a drink
2 [ ] 1 drink
3 [ ] 2 drink
4 [ ] 3 or more drinks
5 [ ] I don't drink alcohol

31. On how many DAYS in the LAST MONTH (30 days) did you have FIVE OR MORE alcoholic drinks?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

32. On how many DAYS in the LAST MONTH (30 days) did you feel drunk?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

The next few questions are about MARIJUANA (Sometimes called dope, grass, weed, pot, smoke, hash, jones, spleef, joint, doobee, herb, sen, sezz, stick, stone, ganja, or cannabis.)

33. How often are you with kids who are using marijuana?

1 [ ] Often
2 [ ] Sometimes
3 [ ] Hardly ever
4 [ ] Never

34. Do you think your best friend uses marijuana sometimes?

1 [ ] Yes
2 [ ] No

35. If your friends found out that you used marijuana sometimes, how do you think they'd feel?

1 [ ] They would approve
2 [ ] They would disapprove but still be my friends
3 [ ] They would disapprove and stop being my friends
4 [ ] They wouldn't care

36. How would your parents feel if they found out you used marijuana sometimes?

1 [ ] Not at all upset
2 [ ] A little upset
3 [ ] Pretty upset
4 [ ] Very upset
5 [ ] They wouldn't care

37. Have you EVER TRIED marijuana?

1 [ ] Yes
2 [ ] No

38. Do you think you will use any marijuana in the next six months?

1 [ ] Definitely yes
2 [ ] Probably yes
3 [ ] Probably no
4 [ ] Definitely no

39. How many times have you been offered marijuana in the past year?

1 [ ] Never
2 [ ] Once
3 [ ] Twice
4 [ ] 3 or 4 times
5 [ ] 5 times or more

40. On how many DAYS did you use any marijuana in the LAST MONTH (30 days)? For example, if you used marijuana each weekend night, that would be 8 days (4 weekends times 2 days each weekend).

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

41. How many DAYS have you used marijuana in the LAST YEAR? For example, if you used marijuana each weekend night, that would be about 100 days (about 50 weekend times 2 days, each weekend).

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

42. On the days you use marijuana, how many times do you use it?

1 [ ] Once a day
2 [ ] Twice a day
3 [ ] 3 or more times a day
4 [ ] I don't use marijuana

43. On how many DAYS in the LAST MONTH (30 days) did you feel high on marijuana?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

The next few questions are about COCAINE and CRACK COCAINE (sometimes called coke, snow, powder, rock, blow, dust, sniff, toot, girl, lady, nose powder, freebase, eggs, fries or snort).

44. How often are you with kids who are using cocaine?

1 [ ] Often
2 [ ] Sometimes
3 [ ] Hardly ever
4 [ ] Never

45. Do you think your best friend uses cocaine sometimes?

1 [ ] Yes
2 [ ] No

46. If your friends found out that you used cocaine sometimes, how do you think they'd feel?

1 [ ] They would approve
2 [ ] They would disapprove but still be my friends
3 [ ] They would disapprove and stop being my friends
4 [ ] They wouldn't care

47. How would your parents feel if they found out you used cocaine sometimes?

1 [ ] Not at all upset
2 [ ] A little upset
3 [ ] Pretty upset
4 [ ] Very upset
5 [ ] They wouldn't care

48. Have you EVER TRIED cocaine?

1 [ ] Yes
2 [ ] No

49. Do you think you will use any cocaine in the next six months?

1 [ ] Definitely yes
2 [ ] Probably yes
3 [ ] Probably no
4 [ ] Definitely no

50. How many times have you been offered cocaine in the past year?

1 [ ] Never
2 [ ] Once
3 [ ] Twice
4 [ ] 3 or 4 times
5 [ ] 5 times or more

51. On how many DAYS did you use cocaine in the LAST MONTH (30 days)?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

52. How many DAYS have you used cocaine in the LAST YEAR?

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

53. On the days you use cocaine, how many times do you use it?

1 [ ] Once a day
2 [ ] Twice a day
3 [ ] 3 or more times a day
4 [ ] I don't use cocaine

54. On how many DAYS in the LAST MONTH (30 days) did you feel high on cocaine?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

The next three questions are about HEROIN (Sometimes called smack, dirt, brown sugar, black tar, H, hard candy, joy powder, scag, or horse).

55. Have you EVER TRIED heroin?

1 [ ] Yes
2 [ ] No

56. On how many DAYS did you use heroin in the LAST MONTH (30 days)?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

57. How many times have you used heroin in the LAST YEAR?

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

The next three questions are about HALLUCINOGENS for example, LSD (sometimes called acid, trip, purple haze, microdot, tab or blotters), or peyote, mescaline, psilocybin (called mushrooms or silly putty), PCP (called angel dust, hog, loveboat, or wack), or MDMA (called ecstasy).

58. Have you EVER TRIED hallucinogens?

1 [ ] Yes
2 [ ] No

59. On how many DAYS did you use hallucinogens in the LAST MONTH (30 days)?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

60. How many times have you used hallucinogens in the LAST YEAR?

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

The next three questions are about AMPHETAMINES (sometimes called speed, uppers, or jelly bean).

61. Have you EVER TRIED amphetamines?

1 [ ] Yes
2 [ ] No

62. On how many DAYS did you use amphetamines in the LAST MONTH (30 days)?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 19 days in the last month.
5 [ ] 20 or more days in the last month.

63. How many times have you used amphetamines in the LAST YEAR?

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

The next three questions are about TRANQUILIZERS, such as Valium, Quaaludes (sometimes called ludes), or Librium (called lib or Mother's little helper).

64. Have you EVER TRIED tranquilizers, other than when prescribed by your doctor?

1 [ ] Yes
2 [ ] No

65. On how many DAYS did you use tranquilizers in the LAST MONTH (30 days), other than when prescribed by your doctor?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

66. How many times have you used tranquilizers in the LAST YEAR, other than when prescribed by your doctor?

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

The next three questions are about BARBITURATES (sometimes called downers, m&m, peanut, red and blue, sleeper, yellow jacket, or red devil)

67. Have you EVER TRIED barbiturates, other than when prescribed by your doctor?

1 [ ] Yes
2 [ ] No

68. On how many DAYS did you use barbiturates in the LAST MONTH (30 days), other than when prescribed by your doctor?

1 [ ] None
2 [ ] 1 or 2 days in the last month.
3 [ ] 3 to 5 days in the last month.
4 [ ] 6 to 9 days in the last month.
5 [ ] 10 to 19 days in the last month.
6 [ ] 20 to 31 days in the last month.

69. How many times have you used barbiturates in the LAST YEAR, other than when prescribed by your doctor?

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

The next three questions are about INHALANTS, that is, substances inhaled to get high, such as amyl and butyl nitrite (sometimes called poppers, snappers, rush, or hardware) or glue, aerosol sprays, gasoline or lighter fluids, ether, correction or cleaning fluids. (Inhalants are sometimes called huff, sniff, whiteout, and whippets)

70. Have you EVER TRIED inhalants?

1 [ ] Yes
2 [ ] No

71. On how many DAYS did you use inhalants in the LAST MONTH (30 days)?

1 [ ] None
2 [ ] 1 or 2 days in the last month
3 [ ] 3 to 5 days in the last month
4 [ ] 6 to 19 days in the last month
5 [ ] 20 or more days in the last month

72. How many times have you used inhalants in the LAST YEAR?

1 [ ] None
2 [ ] 1 or 2 times
3 [ ] 3 to 5 times
4 [ ] 6 to 9 times
5 [ ] 10 to 19 times
6 [ ] 20 to 39 times
7 [ ] 40 to 59 times
8 [ ] 60 to 80 times
9 [ ] More than 80 times

The next questions cover your feelings about and experiences with using alcohol and drugs.

73. Pretend your best friend offered you a drink of beer or wine and you did not want it. How hard would it be to refuse the offer?

1 [ ] Very easy
2 [ ] Pretty easy
3 [ ] Pretty hard
4 [ ] Very hard

74. Pretend your best friend offered you a drink of beer or wine and you did not want it. How sure are you that you could say "no"?

1 [ ] Very sure
2 [ ] Pretty sure
3 [ ] A little unsure
4 [ ] Not sure at all

75. Pretend your best friend offered you some marijuana and you did not want it. How hard would it be to refuse the offer?

1 [ ] Very easy
2 [ ] Pretty easy
3 [ ] Pretty hard
4 [ ] Very hard

76. Pretend your best friend offered you some marijuana and you did not want it. How sure are you that you could say "no"?

1 [ ] Very sure
2 [ ] Pretty sure
3 [ ] A little unsure
4 [ ] Not sure at all

77. Pretend your best friend offered you some cocaine and you did not want it. How hard would it be to refuse the offer?

1 [ ] Very easy
2 [ ] Pretty easy
3 [ ] Pretty hard
4 [ ] Very hard

78. Pretend your best friend offered you some cocaine and you did not want it. How sure are you that you could say "no"?

1 [ ] Very sure
2 [ ] Pretty sure
3 [ ] A little unsure
4 [ ] Not sure at all

79. In the past year, how often did you drive when you'd been drinking?

0 [ ] I don't drive.
1 [ ] never
2 [ ] sometimes, but not often
3 [ ] often
4 [ ] all the time

80. In the past year, how often did you ride in a car with a driver who had been drinking?

1 [ ] never
2 [ ] sometimes, but not often
3 [ ] often
4 [ ] all the time

81. In the past year, have you driven when you've been using drugs, such as marijuana or cocaine?

0 [ ] I don't drive.
1 [ ] never
2 [ ] sometimes, but not often
3 [ ] often
4 [ ] all the time

82. In the past year, how often did you ride in a car with a driver who had been using drugs, such as marijuana or cocaine?

1 [ ] never
2 [ ] sometimes, but not often
3 [ ] often
4 [ ] all the time

83. In the past year, how often did you use alcohol just before or while attending school?

1 [ ] never
2 [ ] sometimes, but not often
3 [ ] often
4 [ ] all the time

84. In the past year, how often did you use drugs, such as marijuana or cocaine, just before or while attending school?

1 [ ] never
2 [ ] sometimes, but not often
3 [ ] often
4 [ ] all the time

85. Have you ever sold drugs?

1 [ ] Yes
2 [ ] No

86. How often have you sold drugs in the past year?

1 [ ] never
2 [ ] sometimes, but not often
3 [ ] often
4 [ ] all the time

87. Pretend your best friend asked you to sell drugs and you did not want to. How <u>sure</u> are you that you could say "no"?

1 [ ] very sure
2 [ ] pretty sure
3 [ ] a little unsure
4 [ ] not sure at all

88. a. In the past year, how many times were you in a physical fight?

1 [ ] 0 times
2 [ ] 1 time
3 [ ] 2 or 3 times
4 [ ] 4 or 5 times
5 [ ] 6 or more times

b. In the past year, on the days you had a physical fight, did you use alcohol or drugs?

1 [ ] I was never in a fight
2 [ ] Yes, I sometimes used alcohol or drugs
3 [ ] Yes, I always used alcohol or drugs
4 [ ] No, I never used alcohol or drugs

89. a. In the past year, how many times were you in trouble with the law, that is, arrested or threatened with arrest?

1 [ ] 0
2 [ ] 1
3 [ ] 2 or 3
4 [ ] 4 or 5
5 [ ] 6 or more times

b. In the past year, on the days you were in trouble with the law, did you use alcohol or drugs?

1 [ ] I was never in trouble with the law.
2 [ ] Yes, I sometimes used alcohol or drugs
3 [ ] Yes, I always used alcohol or drugs
4 [ ] No, I never used alcohol or drugs

90. a. In the past year, how many times did you damage or destroy things that did not belong to you (for example, street signs, cars, or neighbor's property)?

1 [ ] 0
2 [ ] 1
3 [ ] 2 or 3
4 [ ] 4 or 5
5 [ ] 6 or more times

b. In the past year, on the days you damaged or destroyed things that did not belong to you, did you use alcohol or drugs?

1 [ ] I never damaged or destroyed things.
2 [ ] Yes, I sometimes used alcohol or drugs
3 [ ] Yes, I always used alcohol or drugs
4 [ ] No, I never used alcohol or drugs

91. a. In the past year, how many times were you in trouble with school officials (for example, poor grades, skipping school, or acting out in class)?

1 [ ] 0
2 [ ] 1
3 [ ] 2 or 3
4 [ ] 4 or 5
5 [ ] 6 or more times

b. In the past year, on the days you were in trouble with school officials, did you use alcohol or drugs?

1 [ ] I was never in trouble with school officials.
2 [ ] Yes, I sometimes used alcohol or drugs
3 [ ] Yes, I always used alcohol or drugs
4 [ ] No, I never used alcohol or drugs

92. How many hours each week are you involved in sports, clubs, or other after-school activities?

1 [ ] None
2 [ ] 1 to 5 hours each week
3 [ ] 6 to 10 hours each week
4 [ ] 11 to 20 hours each week
5 [ ] more than 20 hours each week

93. How many hours do you work each week on an after-school job?

1 [ ] None
2 [ ] 1 to 5 hours each week
3 [ ] 6 to 10 hours each week
4 [ ] 11 to 20 hours each week
5 [ ] more than 20 hours each week

94. How many hours do you work each week at home (chores, cooking, baby sitting family members)?

1 [ ] None
2 [ ] 1 to 5 hours each week
3 [ ] 6 to 10 hours each week
4 [ ] 11 to 20 hours each week
5 [ ] more than 20 hours each week

95. How many hours do you spend with your parents and other adult relatives each week?

1 [ ] None
2 [ ] 1 to 5 hours each week
3 [ ] 6 to 10 hours each week
4 [ ] 11 to 20 hours each week
5 [ ] more than 20 hours each week

96. During the LAST FOUR WEEKS how many whole days of school have you missed?

1 [ ] None
2 [ ] 1 Day
3 [ ] 2 Days
4 [ ] 3 Days
5 [ ] 4 to 5 Days
6 [ ] 6 to 10 Days
7 [ ] 11 or more

APPENDIX E

Form Approved
OMB NO. 0930-XXXX
Exp. Date_____

COMMUNITY SURVEY

COMMUNITY SURVEY

Code #/_/_/_/_/_/_/_/_/_/ Date Interview Began /_/_/ /_/_/ /_/_/
Month Day Year

Site: _____ Time Interview Began /_/_/ /_/_/
Hour Minute

Circle One: AM ... PM

INTRODUCTION AND HOUSEHOLD SCREENER

A. Hello, I'm ___, and I'm working on a study sponsored by the U.S. Department of Health and Human Services and authorized by Section 516 of the Public Health Service Act (IF ASKED FOR REFERENCE: (42USC290bb-22)). I work for a private research firm that is conducting the study for HHS, which is interested in learning more about people's views on alcohol and drug use. Your phone number was chosen at random from those in your community.

B. Am I speaking to an adult member of the household at least 18 years of age?

Yes.....1
No.....2 (Ask for an Adult, REREAD INTRODUCTION AND CONTINUE. IF NOT AVAILABLE, MAKE APPOINTMENT AND RECORD ON CALL RECORD.)

C. First, I'd like to make sure I've dialed the right number.

Is this /_/_/-/_/_/_/-/_/_/_/? (RECORD NUMBER WHILE VERIFYING)
Area Code Telephone Number

Yes.....1
No.....2 Thank you very much, but I seem to have dialed a wrong number. It is possible that your number may be called at a later time. (HANG UP, REDIAL IF NECESSARY.)

D. Is this a residence?

Yes.....1
No.....2 (PROBE AND VERIFY) Thank you very much, but we are only interviewing in private residences. (HANG UP, CODE STATUS APPROPRIATELY.)

E. Do you have any other residential telephone numbers in addition to (NUMBER) ringing in your home?

Yes.....1 (PROBE TO MAKE SURE IT IS NOT AN EXTENSION)
No.....2

F. How many people aged 18-44 are living in your household?_____

G. What is your zip code? /_/_/_/_/_/

H. We need to talk with the person living in your household who is 18-44 years of age and who has had the most recent birthday. Would that be you or someone else at this telephone number?

IF YOU ARE SPEAKING TO THE SELECTED RESPONDENT, READ:
On the basis of the selection procedures we use, you have been randomly selected from your household to participate in this study. (CONTINUE with I.)

IF YOU ARE NOT SPEAKING TO THE SELECTED RESPONDENT, ASK TO SPEAK TO THAT PERSON. IF THE SELECTED RESPONDENT IS AVAILABLE, RE-READ THE INTRODUCTION, (A), THEN CONTINUE WITH I.

IF THE SELECTED RESPONDENT IS NOT AVAILABLE RECORD SELECTED RESPONDENT'S NAME AND THE BEST TIME TO REACH HIM/HER.

I. Your answers to questions we ask will be kept strictly *confidential*; no one but analysts in our firm will ever see your answers. The survey is also *anonymous*; your names will never be connected with the survey -- in fact, we will not even ask your name.

The results of this study will provide the Federal Government with information about how people feel about drug and alcohol use and what to do about it. Remember, it's important that you answer the questions as accurately and frankly as possible.

Please understand that your participation is voluntary, and that if I ask you any questions that you don't want to answer, obviously you don't have to. If it's all right with you, let's get started. (PAUSE TO GIVE RESPONDENT A CHANCE TO ASK QUESTIONS.)

Is this a convenient time for us to conduct the interview?

NO - Would some other time be preferable?
Reschedule and note time and date_____

YES - CONTINUE

I. NEIGHBORHOOD CONDITIONS

First, I would like to ask you about the conditions in your neighborhood -- where you live and the several blocks around you. I'll read a question and then several responses, and I'd like you to tell me which of the responses best answers the question. As with all the questions I'll ask, you don't have to answer any questions that you would really prefer not to answer.

1. In your opinion, do many people in this neighborhood use drugs?

(Read the responses and mark one circle.)

- Yes, many residents use drugs. ○
- There's some drug use, but not a lot ○
- Not many people use drugs in this neighborhood ○
- There's no drug use in this neighborhood ○

2. How often do you see drug dealing in this neighborhood?

(Read the responses and mark one circle.)

- Very often ○
- Sometimes ○
- Rarely ○
- Never ○

3. During the day, how safe do you feel being out alone in your neighborhood?

(Read the responses and mark one circle.)

- Very safe ○
- Fairly safe ○
- Somewhat safe ○
- Very unsafe ○

4. After dark, how safe do you feel being out alone in your neighborhood?

(Read the responses and mark one circle.)

Very safe ..... ○

Fairly safe ..... ○

Somewhat unsafe ..... ○

Very unsafe ..... ○

5. How much of a problem are drugs in your neighborhood?

Major problem ..... ○

Minor problem ..... ○

No problem ..... ○

6. Do you live in the same neighborhoods as you did one year ago?

Yes (*continue*) ..... ○

No (*go to question #11*) ..... ○

7. Compared to <u>one year ago</u>, do you now feel more safe or less safe in your neighborhood?

(Read the responses and mark one circle.)

Much less safe than before ..... ○

A little less safe than before ..... ○

About the same as before ..... ○

A little more safe than before ..... ○

Much more safe than before ..... ○

8 Compared to one year ago, has your neighborhood become a better or a worse place to live?

(Read the responses and mark one circle.)

- Much worse than before ..... ○
- A little worse than before ..... ○
- About the same as before ..... ○
- A little better than before ..... ○
- Much better than before ..... ○

9. Compared to one year ago, has drug dealing changed in your neighborhood?

- Much worse dealing than before ..... ○
- A little worse dealing than before ..... ○
- About the same as before ..... ○
- A little less dealing than before ..... ○
- Much more dealing than before ..... ○
- Never existed ..... ○

10. Compared to one year ago, how much of a problem are drugs in your neighborhood?

- Much worse than before ..... ○
- A little worse than before ..... ○
- About the same as before ..... ○
- A little better than before ..... ○
- Much better than before ..... ○

11. Are there alternative activities to alcohol and drugs for youth in your neighborhood?

- Many activities ..... ○
- Some activities ..... ○
- Few activities ..... ○
- None ..... ○

12. In your opinion, do people in your neighborhood feel they are able to have control over the use of drugs in the neighborhood, that is, they are able to keep drug use to a minimum?

Yes, they feel a great deal of control ..... ○

Yes, they feel they have some control ..... ○

No, they feel they have little control ..... ○

No, they feel they have no control ..... ○

13. Are the people in your neighborhood actively involved in preventing drug use or stopping drug use?

Yes, they are involved to a great extent ..... ○

Yes, they are involved somewhat ..... ○

No, there is little involvement ..... ○

No, they are not involved ..... ○

14. Have you seen or heard alcohol or drug prevention messages (for example, posters, pamphlets, radio or TV ads) in the past six months in your area?

○ No - *Go to Question #17*

○ Yes - continue

15. Who sponsored the alcohol or drug prevention messages you have seen or heard?

(list)_____

○ Don't know

16. Where did you see or hear the alcohol or drug prevention messages?

○ Home

○ Work

○ School

○ Other (specify)_____

17. Have you participated in an alcohol or drug prevention program in the past six months in your area?

- ○ No - *Go to question #20*
- ○ Yes - continue

18. Who sponsored the alcohol or drug prevention program you participated in?

(list) _____

- ○ Don't know

19. Where did you participate in the alcohol or drug prevention program?

- ○ Home
- ○ Work
- ○ School
- ○ Other (specify)_____

II. ATTITUDES ON ALCOHOL AND DRUG USE

Next, I'd like to ask you about your attitudes toward drinking and drug use.

20. Individuals differ in whether or not they disapprove of people doing certain things. I'd like you to tell me whether you disapprove of people who are above the drinking age doing each of the following behaviors. I'll describe a drinking behavior; you should tell me if you "Think it's OK," "Disapprove" or "Strongly disapprove" of that behavior. Do you understand what I'd like you to do?

(Mark one circle for each line)

	It's OK	Disapprove	Strongly Disapprove
a. Having one or two drinks (beer, wine, liquor or mixed drink) in the evening?	○	○	○
b. Having three or four drinks in the evening?	○	○	○
c. Having five or more drinks in the evening?	○	○	○
d. Getting drunk on occasion?	○	○	○
e. Getting drunk regularly?	○	○	○

21. Next I'll ask how much you think people risk harming themselves physically and in other ways when they drink alcohol in certain amounts. I'll describe a certain drinking behavior and you should tell me if you think that behavior poses "No risk," "A slight risk," "A moderate risk," or "A great risk."

(Mark one circle for each line.)

	No Risk	Slight Risk	Moderate Risk	Great Risk
a. Have one or two drinks nearly every day?	○	○	○	○
b. Have four or five drinks nearly every day?	○	○	○	○
c. Have five or more drinks once or twice a week?	○	○	○	○

22. Now I'd like you to tell me if you "Think it's OK," "Disapprove," or "Strongly disapprove" of people doing each of the following behaviors.

(Mark one circle for each line.)

	It's OK	Disapprove	Strongly Disapprove
a. Smoking one or more packs of cigarettes per day	○	○	○
b. Trying marijuana (pot, grass) once or twice	○	○	○
c. Smoking marijuana regularly	○	○	○
d. Trying cocaine or crack once or twice	○	○	○
e. Taking cocaine or crack regularly	○	○	○
f. Trying an amphetamine (upper, pep, ice pill, bennie, speed) once or twice	○	○	○
g. Taking amphetamines regularly	○	○	○
h. Trying barbiturates (downer, goofball, red, yellow, etc.) once or twice	○	○	○
i. Taking barbiturates regularly	○	○	○
j. Trying heroin (smack, horse) once or twice	○	○	○
k. Taking heroin regularly	○	○	○
l. Trying LSD once or twice	○	○	○
m. Taking LSD regularly	○	○	○

23. How much do you think people risk harming themselves physically and in other ways when they do each of the following activities? Please respond with either "No risk," "A slight risk," "A moderate risk," or "A great risk."

(Mark one circle for each line.)

	No Risk	Slight Risk	Moderate Risk	Great Risk
a. Try marijuana once or twice?	O	O	O	O
b. Smoke marijuana occasionally?	O	O	O	O
c. Smoke marijuana regularly?	O	O	O	O
d. Try cocaine powder once or twice?	O	O	O	O
e. Use cocaine powder occasionally?	O	O	O	O
f. Use cocaine powder regularly?	O	O	O	O
g. Try "crack" cocaine once or twice?	O	O	O	O
h. Use "crack" cocaine occasionally?	O	O	O	O
i. Use "crack" cocaine regularly?	O	O	O	O

24. How difficult do you think it would be for you to get each of the following types of drugs, if you wanted some? After I list each type of drug, please respond with either "Very difficult," "Fairly difficult," "Fairly easy," or "Very easy."

(Mark one circle for each line.)

	Very Difficult	Fairly Difficult	Fairly Easy	Very Easy	Don't Know
a. Marijuana (pot, grass)	O	O	O	O	O
b. "Crack" cocaine	O	O	O	O	O
c. Other forms of cocaine	O	O	O	O	O
d. Heroin	O	O	O	O	O
e. Some other narcotic (methadone, opium, codeine, paregoric, etc.)	O	O	O	O	O
f. Tranquilizers	O	O	O	O	O
g. Barbiturates (downers, goofballs, reds, yellows, etc.)	O	O	O	O	O
h. Amphetamines (uppers, pep pills, bennies, speed)	O	O	O	O	O
i. LSD	O	O	O	O	O

V. DRINKING

Next, I want to ask you about drinking alcoholic beverages, including beer, wine, liquor and mixed alcoholic drinks. By a drink, we mean a can of beer, a glass of wine, a wine cooler, or a drink with hard liquor. These questions refer to the use of alcohol for other than religious purposes.

25. Have you had a drink in the past 12 months?

(Mark one circle)

○ No -- *Go to Question #35*

○ Yes -- CONTINUE

26. On about how many different days did you have one or more drinks during the past 30 days?
(IF NONE IN THE PAST 30 DAYS, WRITE ZERO.)

Number of days drank alcohol in past month..... _____

27. About how many drinks did you usually have in a day on the days that you drank during the past 30 days? *(IF NONE IN THE PAST 30 DAYS, WRITE ZERO.)*

Usual number of drinks per day in past month..... _____

28. On about how many days did you have five or more drinks on the same occasion during the past 30 days? By occasion we mean at the same time or within a couple of hours of each other.
(IF NONE IN THE PAST 30 DAYS, WRITE ZERO.)

Number of days you drank five or more drinks..... _____

29. On the average, how often in the last 12 months have you had any alcoholic beverage, that is, beer, wine, or liquor?
(Mark one circle.)

Daily ..... ○
Almost daily or 3 to 6 days a week ..... ○
Several times a month (about 25 to 51 days a year) ..... ○
1 to 2 times a month (12 to 24 days a year) ..... ○
Every other month or so (6 to 11 days a year) ..... ○
3 to 5 days in the past 12 months ..... ○
1 or 2 days in the past 12 months ..... ○
Did not drink alcohol in the past 12 months ..... ○

Now I'd like to ask you some questions about things you might have experienced during the past year as a result of your drinking. After I read each question, please respond with **never, rarely, sometimes, frequently,** or **always** -- depending upon your particular experience.

(Read the following questions and circle the number according to the respondent's answer. After each question, repeat the response categories.)

	NEVER	RARELY	SOMETIMES	FREQUENTLY	ALWAYS
30. Do you ever feel the need to cut down on your drinking?	1	2	3	4	5
31. Do friends or family criticize or express concern about your drinking?	1	2	3	4	5
32. Do you have difficulty recalling events which occurred while you were drinking?	1	2	3	4	5
33. Is it difficult for you to stop drinking once you start?	1	2	3	4	5
34. As a result of your drinking, have you experienced social or legal problems?	1	2	3	4	5

IV. DRUG USE

35. Next, I'm going to name several types of drugs. If you have used the drug in the past twelve months, simply say *"yes"* right after I name the drug. If you have not used the drug in the past twelve months, simply say *"no"* right after I name the drug. So as I name each drug you will say *"yes"* or *"no"*. Okay? If you have any questions at all as I name these drugs, please stop and ask me.

(First, proceed down the drug list, placing a "Y" or "N" beside the drug.)

(Second, after completing the list, for each "Y", pull out a "Drug Patterns" answer sheet, write in the drug type, and proceed through the questions.)

DRUG TYPE LIST

_____ Marijuana or hashish

_____ Cocaine or Crack

_____ Tranquilizers (e.g., valium, librium, xanax)

_____ Sedatives (e.g., barbiturates, downers)

_____ Analgesics (e.g., percodan, darvon)

_____ Stimulants (e.g., uppers, speed, amphetamines)

_____ Inhalants (*e.g., gasoline, paints*)

_____ Heroin

_____ Other opiates (e.g., morphine)

_____ Hallucinogens (e.g., LSD, PCP, peyote)

(If the respondent did not answer "Yes" to any drug, proceed to the next section (VI) on demographics

Reference Sheet for Interviewers
SPECIFIC DRUG NAMES

INHALANTS

Gasoline or lighter fluids
Spray paints
Other aerosol sprays
Shoe shine, glue or toluene
Lacquer thinner or other paint solvents
Amyl nitrite, "Poppers," locker room deodorizer, "Rush"
Halothane, ether, or other anesthetics
Nitrous oxide, whippets
Correction fluids, degreasers, cleaning fluids

HALLUCINOGENS

LSD
Peyote
Mescaline
Psilocybin (Mushrooms)
PCP (Angel Dust)
"Ecstasy" (MDMA)

STIMULANTS

Dexedrine
Dexamyl
Eskatrol
Benzedrine
Biphetamine
Desoxyn
Dextroamphetamine
Obedrin-L.A.
Tenuate
Methedrine
Methamphetamine
"Ice"
Tepanil
Didrex
Plegine
Preludin
Cylert
Ionamin
Pondimin
Sanorex
Ritalin
Voranil
Fastin

TRANQUILIZERS

Valium
Librium
Menrium
Serax
Tranxene
Ativan
Durrax
Diazepam
Deprol
Limbitrol
Equanil
Meprobamate
Vistaril
Atarax
Xanax
Miltown
Buspar
Sk-lygen
Paxipam

SEDATIVES

Butisol
Placidyl
Buticaps
Doriden
Amytal
Noludar
Secobarbital
Halcion
Mebaral
Amobarbital
Phenobarbital
Sopor
Darvon
Quaalude
Dalmane
Restoril
Methaqualone
Chloral Hydrate
Nembutal
Tuinal
Pentobarbital
Seconal

ANALGESICS

Tylenol with Codeine
Dolene
SK-65
Levo-dromoran
Demerol
Methadone
Propoxyphene
Wygesic
Levo-dromoran
Percodan
Codeine
Percodan
Dilaudid
Talwin
Talwin NX
Anilridine
Talacen
Phenophen with

DRUG PATTERNS AND EXPERIENCES

Type of Drug_____

(If the drug is a prescription type drug, see if the respondent's use fits the definition of non-medical use before proceeding with the questions)

Non-medical use:

1. without a doctor's prescription, or
2. in greater amounts, or
3. more often, or
4. for any reasons other than a doctor said that you should take them -- such as for kicks, to get high, to feel good, or curiosity about the pill's effect.

[ASK QUESTIONS 36-41 FOR EACH DRUG]

Now, I'd like to ask you some details about your use of this drug. The first two questions ask about how often you've used the drug in the past 30 days. I'll ask you the question, then state a frequency like "daily". As I state the frequency you say "yes" if that describes your use. Okay?

(Circle the code that elicits a "yes" for the question.)

36. How often have you used this drug in the past *30 days?*

...Daily	1
...Almost daily or 3 to 6 days a week	2
...About 1 or 2 days a week	3
...Several times a month	4
...1 to 2 times a month	5
...No use in the past 30 days	6

37. How often have you used this drug in the past 12 months?

...Daily	1
...Almost daily or 3 to 6 days a week	2
...About 1 or 2 days a week	3
...Several times a month	4
...1 to 2 times a month	5
...Every other month or so	6
...1 or 2 days in the past 12 months	7
...Not at all in the past 12 months	8

Next, I'd like to ask you some questions about things you might have experienced during the past year as a result of taking this drug. After I read each question, please respond with never, rarely, sometimes, frequently, or always - depending upon your particular experience.

(Read the following questions and circle the numbers according to the respondent's answer. After each question, repeat the response categories.)

	NEVER	RARELY	SOMETIMES	FREQUENTLY	ALWAYS
38. Does the use of this drug cause you legal or social problems?	1	2	3	4	5
39. Do you sometimes feel guilty or concerned about your use of this drug?	1	2	3	4	5
40. Are you able to stop using the drug easily?	1	2	3	4	5
41. Do friends or family criticize your use of this drug?	1	2	3	4	5

V. CIRCUMSTANCES OF USE

For the final questions, I'll ask how often you drink alcohol or use other drugs while driving or before or at work, and I'd like you to respond "never," "sometimes but not often," "often" or "all the time".

42. In the past year, how often did you drive when you'd been drinking alcohol?

(CHECK ONE BOX)

1 [ ] do not drive
2 [ ] never
3 [ ] sometimes, but not often
4 [ ] often
5 [ ] all the time

43. In the past year, how often did you drive when you'd been using marijuana, cocaine, or other such drugs?

(CHECK ONE BOX)

1 [ ] do not drive
2 [ ] never
3 [ ] sometimes, but not often
4 [ ] often
5 [ ] all the time

44. In the past year, how often did you drink alcohol just before or while at work?

(CHECK ONE BOX)

1 [ ] have not had a job in the past year
2 [ ] never
3 [ ] sometimes, but not often
4 [ ] often
5 [ ] all the time

45. In the past year, how often did you use marijuana, cocaine, or other such drugs just before or while at work?

(CHECK ONE BOX)

1 [ ] have not had a job in the past year
2 [ ] never
3 [ ] sometimes, but not often
4 [ ] often
5 [ ] all the time

VI. DEMOGRAPHICS

Now, I'd like to ask some questions about you. As with all the questions I've asked, you don't have to answer any questions that you would really prefer not to.

46. What is your age? _____

47. What is your sex? ☐ Male ☐ Female

48. What is your marital status? ☐ Married ☐ Divorced ☐ Single ☐ Separated

49. Which of the following categories best describes the amount of school you completed?

☐ less than high school graduation
☐ high school graduation
☐ some college
☐ a bachelors degree or higher

50. Would you classify yourself as: *(read categories)*

☐ White, not of Hispanic origin
☐ Black, not of Hispanic origin
☐ Asian or Pacific Islander
☐ Hispanic
☐ American Indian or Alaskan Native
☐ Other (specify)_____

51. Which of the following categories best describes your annual household income before taxes last year?

☐ less than $12,000
☐ 12,000 to 19,999
☐ 20,000 to 29,999
☐ 30,000 to 39,999
☐ 40,000 to 49,999
☐ 50,000 or over

THAT'S ALL THE QUESTIONS I HAVE.

THANK YOU VERY MUCH FOR YOUR TIME AND PARTICIPATION.

PAPERWORK DOCKET WORKSHEET PAGE 1

OMB NO: 0930-0166 DATE RECD: 10/22/93
REQUEST CLASS: NEW PENDING
AGENCY: Substance Abuse and Mental Health Services Administration
DEPARTMENT: Department of Health and Human Services
AGENCY FORM NO(S):
OLD TITLE:

NEW TITLE: EVALUATION OF JOB CORPS DRUG TREATMENT ENRICHMENT PROGRAM (DTEP)

ABSTRACT:
DRUG TREATMENT, PROGRAM EVALUATION
CSAT IS SPONSORING A 4-YEAR DRUG TREATMENT INTERVENTION DEMONSTRATION PROJECT WITH THE U.S. DEPARTMENT OF LABOR, OFFICE OF THE JOB CORPS. THE DTEP PROJECT HAS BEEN IMPLEMENTED IN 4 EXPERIMENTAL CENTERS AND DESIGNED AS AN ENHANCEMENT OF AN EXISTING PROGRAM WITH THE ADDITION OF STAFF. THE EVALUATION WILL DRAW UPON INFORMATION INTEGRAL TO STUDENT ASSESSMENT AND THE PROCESS OF PROVIDING STUDENT SERVICES. A FOLLOW-UP INTERVIEW WILL BE CONDUCTED 12 MONTHS AFTER PROGRAM TERMINATION.

ALLOWANCE LETTER: NO 3504(H): N/A
ON PLAN: NO**** EXCEED BUDGET: NO NO. OF FORMS: 1
AFFECTED PUBLIC: INDVL OR HH
USE: PUBLIC SMALL BUSINESS: NO
PURPOSE: PROG EVAL
FREQUENCY: NON-RECURRING
COLLECTION METHOD: MAIL SELF-ADMIN
RETENTION PERIOD: COLLECTION AGENT: RQSTING AGCY
COMPULSORY STATUS: VOLUNTARY
CONFIDENTIALITY: NO FEDERAL COST: $0 PUBLIC COST:

RESPONDENTS: 0 RESPONSES: 0 HOURS: 0
REVIEWER: Allison Eydt
LAST ACTION: DATE: EXPIRATION DATE:

EXISTING TERMS OF CLEARANCE:

EVALUATION OF JOB CORPS TREATMENT ENRICHMENT DEMONSTRATION (DTEP)

ABSTRACT

The Center for Substance Abuse Treatment (CSAT) is sponsoring a four year drug treatment intervention demonstration project in conjunction with the U.S. Department of Labor, Office of Job Corps. Job Corps is a comprehensive, residential youth education and training program which includes basic education, vocational skills training and work experience. These services are supported by health education, counseling, medical services, allowance payments and structured residential and recreation programs. There are 107 Job Corps centers nationwide which annually enroll approximately 60,000 economically disadvantaged young people between the ages of 16 and 22.

In early 1991, CSAT recognized the potential for conducting a drug use intervention demonstration within a sample of Job Corps centers, given the relatively high risk adolescent population and the residential component of the Job Corps program. For CSAT, the Job Corps demonstration adds an important adolescent program evaluation to the complement of CSAT drug treatment programs and research. Through this demonstration, CSAT and the Office of Job Corps have the opportunity to gain information as to the effectiveness of the enhanced service for curbing substance use among the Job Corps student population.

The drug treatment enrichment project (DTEP), which has been implemented within the four experimental Job Corps centers was designed as an enhancement for the existing intervention program with the provision of five new personnel: Assessment Specialist, Substance Specialist, Education Specialist, Activities Specialist and a Project Assistant. Based on the behavioral models of empowerment and self-efficacy, DTEP was designed to provide a comprehensive assessment for all in-coming students and, for students with serious substance abuse problems, extensive individual and group counseling, remedial education, life skills seminars and an expanded activities program. Case management methods are also pivotal to the DTEP design. An additional four Job Corps centers have been designated as the control centers and have implemented the expanded intake assessment component.

The purpose of the DTEP evaluation is to provide CSAT and the Office of Job Corps with information about the costs and benefits of using enriched drug intervention services within Job Corps centers. The evaluation was designed to address two research questions:

- What is the impact of enriched drug intervention services on process-related indicators such as drop-out rates and disciplinary problems?
- What is the impact of enriched drug intervention services on Job Corps outcome indicators such as GED completion, vocational skill outcomes, student placement rates and student earnings?

The evaluation is comprised of three components, each with its own data collection and analysis plans. These components and the types of required data include:

- Student outcomes while on center: patterns of drug and alcohol use, drop-out rates, vocational outcomes, reading and math gains
- Post-Job Corps student outcomes: drug and alcohol use, criminal justice involvement, employment and earnings
- Program operations assessment: DTEP implementation process; program components and activities; comparability of staff, facilities, record-keeping systems across centers; program costs.

The evaluation will draw upon information which is integral to the student assessments and the process of providing student services.

A follow-up interview, to be conducted 12 months after Job Corps program termination, is proposed for all students who received DTEP services and a sample of students who did not receive these services (control centers). The follow-up interview will collect information about drug and alcohol use, criminal activity, physical and mental health, employment, housing and family relationships. A 20 percent sub-sample of all students included in the follow-up will be requested to provide a urine specimen immediately following the follow-up interview. The purpose of the urine specimen collection is to provide physical verification of self-reported drug use. OMB clearance is being sought for the follow-up survey. The primary purpose of the OMB clearance package is to provide comprehensive information about the follow-up survey within the context of the overall evaluation.

APPENDIX D
INFORMED CONSENTS

Process to Administer Consent Informs

1. Copy of original parent consent obtained while student was enrolled in Job Corps
2. Inform parent or guardian of student selection in study
3. Obtain parent or guardian consent via post card or verbal informed consent
4. Review Consent Booklet
5. Prior to interview, Field Interviewer obtains student's consent to participate
6. After interview, Field Interviewer, if requested, obtains signed release for urine sample.

JOB CORPS DRUG TREATMENT ENRICHMENT PROJECT EVALUATION INFORMED CONSENT FORM

The purpose and procedures of the Job Corps Drug Treatment Enrichment Project Evaluation have been explained to me. I understand the purpose of this research is to find out whether a new drug treatment project will help Job Corp students who are using alcohol or drugs when they come into Job Corps. Information is being collected on students who have not been identified as using alcohol or drugs as well as on students who have been identified as using them.

This information will include questions about my participation in Job Corps, my alcohol and drug use, family, work, school, delinquency, health and mental health. If I am selected to participate in the follow-up study after I leave Job Corps, I will be paid $20 for completing the interview at that time.

My participation in this study and my providing information for the forms and questionnaires is strictly voluntary. My enrollment in any Job Corps program or receipt of any service will not depend on or be affected by my participating in this study and giving information asked for in the forms and questionnaires. If there are specific questions which I do not wish to answer, they can be skipped. I will not be penalized for refusing to provide any part or all of the information requested. I can refuse to participate at any point in the study and will suffer no penalty. Any information I provide will always be grouped with others so that I cannot be identified. My name will not come to the attention of representatives of the Federal government.

The study is being conducted by Caliber Associates and the Research Triangle Institute (RTI) under Contract 270-91-0015, for the Federal Center for Substance Abuse Treatment, Department of Health and Human Services. Caliber and RTI are allowed to ask for information on different forms under Section 509G of the Public Health Services Act (42 U.S.C. 290 aa-14).

I understand that a Federal Certificate of Confidentiality has been obtained to legally and specifically protect the confidentiality of the information obtained in this research and protect my identity. This Certificate will protect the investigators from being forced to release any data in which I am identified, even under a court order or subpoena. I understand that the Certificate expires at the end of (MONTH, YEAR), but the protection for any information RTI collects before then is permanent.

My signature below indicates that the purposes and procedures for the Job Corps Drug Treatment evaluation have been fully explained to me and I consent to participate.

Signature of student:_____ Date:_____

Signature of parent/legal guardian:_____ Date:_____

Signature of interviewer:_____ Date:_____

If I am under 18 years of age when I am selected to participate in the follow-up study after I leave Job Corps, Caliber/RTI does___ does not___have my permission to contact my parent or guardian to obtain their permission to interview me.

Signature of student:_____ Date:_____

Name of parent/guardian:_____

Address:_____

_____

Telephone:_____

LETTER TO OBTAIN PARENTAL OR GUARDIAN CONSENT

Student ID Number

Dear (parents or guardian of student name):

The purpose of this letter is to inform you that your son/daughter has been chosen to participate in the national evaluation of the Job Corps Drug Treatment Enrichment Program (DTEP). When your child was in Job Corps, you signed a form stating that you agreed to let your son/daughter participate in this study. An interviewer from the Research Triangle Institute would like to come and talk to him/her about his/her experiences since leaving Job Corps.

The interview will last approximately one hour and get information from him/her on topics such as employment, living arrangements, health and drug or alcohol use. He/she may also be asked to give the interviewer a urine sample. Your child will be paid $20.00 for participating in the interview, and if requested, paid $10.00 for providing a urine sample.

The information provided by your child will be held strictly confidential and by law will not be shared with anyone except in the form of a report where information will always be grouped so that your child cannot be identified.

If you agree to let your child continue to participate in this important study, please mail us the enclosed, self addressed post card. Thank you very much for your cooperation.

Sincerely,

Project Manager

[THIS FORM WILL BE USED AS STATE LAW REQUIRES]

GENERAL INFORMED CONSENT
PARENT OR GUARDIAN

Student ID Number

By signing and returning this postcard, I agree to let my child participate in the national evaluation of the Drug Treatment Enrichment Project (DTEP). I understand that my son/daughter will be compensated for his/her time.

_____ _____

(Signature of parent or guardian) *(Date)*

_____

(Signature of Person Obtaining Consent)

If parent or guardian does not return the post card, RTI will telephone the parent and obtain a verbal informed consent. A copy of the consent will be mailed to the parent or guardian. A sample of the verbal consent is provided on the following page.

CONFIRM ADDRESS AND MAIL PARENT OR GUARDIAN COPY OF CONSENT FORM

INFORMED PARENTAL CONSENT FOR EVALUATION OF THE DRUG TREATMENT ENRICHMENT PROJECT

An Evaluation of the Drug Treatment Enrichment Project is being conducted by Caliber Associates and Research Triangle Institute (RTI) for the Center for Substance Abuse Treatment. We are studying ways in which drug treatment programs can help adolescents who have been in Job Corps. For this study, we are talking to adolescents may or may not have been in a drug treatment program while they were enrolled in Job Corps.

During this interview, I will ask your child questions about his/her employment history, living situation, use of tobacco, and other substances, and health. This study will provide information to CSAT on ways they can help adolescents successfully train for jobs.

We will keep all your child's information strictly confidential. I will not be able to tell you what your child says during the interview. His/her answers will never be linked to his/her name, and his/her answers will be used only by research staff at Caliber and reported in group format, it will be impossible to tell what any particular person said. His/her name and any other identifying information will never be released to anyone who is not connected with the research study.

Your child's participation in this study is voluntary. If he/she chooses to participate, he/she may stop participating at any time, and he/she has the right to refuse to answer any question that he she does not want to answer. I'll answer any questions that you or your child may have about the survey before we begin. If you or your child have any questions about the study after the interview is conducted, you may call Ms. Judy Lynch toll-free at 1-800-***-****. If you or your child have questions about your rights as a study participant, you should call Dr. Janet Griffith at 1-800-334-8571, ext. 6636.

A Federal Certificate of Confidentiality has been obtained to legally and specifically protect the confidentiality of the information obtained in this research. The Certificate is intended to protect the identity of your child from any person not directly connected with the conduct of the research. The Certificate will protect the investigators from being forced to release any research data, even under a court order or subpoena. The Certificate expires at the end of (MONTH, YEAR), but the protection for any information RTI collects before then is permanent.

If you decide to give permission for your child to be interviewed for this study, I'll sign my name at the bottom of this form in order to show that you understand the kinds of questions I'll be asking your child, how long the interview will take and that your child's participation is voluntary. Do you have any questions?

INTERVIEWER'S SIGNATURE_____ DATE: __/__/__

Informed Consent Booklet

(To be shown to respondent prior to administration of the informed consent)

IMPORTANT POINTS

→ Your participation is completely voluntary. You do not have to participate. Nothing bad will happen to you if you don't participate.

→ You will not have to answer any question you don't want to. It is better not to give an answer which is not the truth.

→ All of your answers will be completely confidential. Only the research companies will know what you said. Any information you provide will be grouped with information from other students for the research reports.

→ The research companies are required by law to keep all the information collected about you completely confidential. A Federal Certificate of Confidentiality has been obtained which protects all the information about you; no one can be forced to release the research data even under a court order.

EVALUATION OF THE DEMONSTRATION DRUG TREATMENT ENRICHMENT PROJECT AT TEN SELECTED JOB CORPS CENTERS

A research study is being conducted to find out how Job Corps can best help students who use alcohol and drugs.

This study is being conducted by private research companies -- Caliber Associates and Research Triangle Institute -- under contract to the Federal government.

WE NEED YOUR HELP IN THIS STUDY, WHETHER OR NOT YOU HAVE USED ALCOHOL OR DRUGS.

HERE'S HOW →

ALL STUDENTS WILL BE REQUESTED TO PARTICIPATE IN THIS STUDY.

You will be asked to:

1) Complete an interview in 3 months or when you leave the center. This interview will include questions about your:
   - o Experiences in Job Corps
   - o Alcohol and drug use
   - o Involvement with the police/criminal activity
   - o Physical and mental health

   It will take you about 1/2 hour to complete.

2) The research companies will stay in touch with you so they can conduct a follow-up interview with you 1 year after you leave Job Corps.

STUDENTS WILL BE RANDOMLY SELECTED BY THE RESEARCH COMPANIES TO PARTICIPATE IN THE FOLLOW-UP STUDY.

IF YOU ARE SELECTED FOR THE 1 YEAR FOLLOW-UP STUDY:

- o An interviewer will write or call you to set up an appointment to interview you.

- o The interview will cover questions about your:
  - Work experiences since leaving Job Corps
  - Alcohol and drug use
  - Involvement with the police/criminal activity
  - Physical and mental health

- o You will be paid $20 for the interview.

- o You may be asked to provide a urine sample. If you do, you will be paid an additional $10.

- o Information about you will also be collected from law enforcement and employment agencies to verify the information you give in the interview.

- o If you are under 18 years of age when it is time for the 1 year follow-up interview, the research companies will need to contact your parent/ guardian to get permission to interview you.

EVALUATION OF THE DRUG TREATMENT ENRICHMENT PROJECT
CONSENT TO PARTICIPATE

NAME: _____

While I was in the Job Corps program, I signed a form indicating that I consented to being contacted for a follow-up interview with a trained interviewer after I left Job Corps. I agree by signing below, to continue to be in the research study conducted by Caliber Associates, Research Triangle Institute and Battelle.

I will be asked about drug or alcohol use, my employment, my health, and living arrangements. The interview will take approximately an hour. I will receive $20.00 at the end of the interview. If I give a sample of my urine, I will be given an additional $10.00.

The information from this study will help answer questions about the helpfulness of having a Drug Treatment Enrichment program in Job Corps or a program like Job Corps. What I say will be very helpful to this study. It will give researchers information that will help design programs for young people.

I understand that a Federal Certificate of Confidentiality has been obtained to legally and specifically protect the confidentiality of the information obtained in this research. This Certificate is intended to protect my identity from any person not directly connected with the conduct of the research. This Certificate will protect the investigators from being forced to release any research data in which I am identified, even under a court order or subpoena. The Certificate does not prevent me from voluntarily disclosing what I have said here. I understand that the Certificate expires at the end of (MONTH, YEAR), but the protection for any information RTI collects before then is permanent. I understand that my participation will not subject me to any foreseeable risks.

We will keep all your information strictly confidential. Your answers will never be linked to your name, or to the names of anyone else in your household. Your answers will be used only by research staff at RTI and Caliber. Your name and any other identifying information will never be released to anyone who is not connected with the research study. Reports of information gathered in this study will be presented only in group reports. In these reports, it will be impossible to tell what any particular person said.

My involvement is completely voluntary. I may refuse to be in this study or may withdraw my consent at any time. I can choose not to answer any question.

I have received a copy of this consent form.

_____ _____

SIGNED RELEASE FOR URINE SAMPLE

I agree to release a sample of my urine to _____ from
(Interviewer Name)
Research Triangle Institute. I understand that the purpose of the urine test is to verify my responses concerning my use of substances. The project staff will not reveal my identity in any civil, criminal or other matter.

My involvement is completely voluntary. I acknowledge that I have been paid $10.00 for the urine sample.

I have received a copy of this consent form.

_____ _____

(Signature of respondent/date) *(Signature of interviewer/date)*

A11. SENSITIVE QUESTIONS: Provide additional justification for any questions of a sensitive nature.

Substance abuse treatment programs, such as the DTEP demonstration, are designed to alter behaviors in areas commonly considered to be sensitive and private. Only through a full understanding of the extent of substance abuse and how it affects an individual's life before and after treatment can success or shortfall of the enriched treatment program be ascertained.

Many of the questionnaire items, such as those on income and employment, use standard wording and are not deemed threatening. Those items dealing with substance use have been adapted from the NTIES instrumentation for use with this population.

A pilot test of the IAP-I questionnaire (which contains many of the same questions on substance abuse, criminal activity and related behaviors) showed that most of the students tested were not uncomfortable about answering questions on sensitive topics. Most of those in the pilot test thought that others their own age would not have difficulties answering the question.

Interviewer training will stress the sensitive nature of the interview and provide instruction on maintaining a non-threatening, non-judgmental tone to the interview. The objective will be to reduce respondents' sense of discomfort and sensitivity.

Follow-up data will also be collected from a sub-sample of respondents who will be requested to provide urinalysis specimens. While the collection of urine specimens may be considered to be intrusive, the interviewers will emphasize to the respondents that this is both optional and completely confidential. Respondents will experience no consequences as a result of their urinalysis, and will be informed that this is the case.

Given that no single type of data gives 100 percent accurate information about the behavior being studied, both self-report and urinalysis data will be requested for this research. Urinalysis is important because it is the most objective method for finding what types of drugs have recently been ingested. Self-report is less intrusive and it may provide data on substances which have been metabolized before urinalysis. However, self-report data may be affected by social desirability bias or forgetfulness. Each type of data provides a check on the other. The degree to which responses converge indicates the reliability and validity of the data.

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

MR. ROBERT POLSON 02/14/95
DEPARTMENT OF HEALTH AND HUMAN SERVIES
ROOM 531-H, HUBERT H. HUMPHREY BUILDING
WASHINGTON, DC 20201

In accordance with the Paperwork Reduction Act, OMB has taken the following action on your request for approval of a new information collection received on 11/18/94.

TITLE: **EVALUATION OF THE COMPREHENSIVE MENTAL HEALTH SERVICES PROGRAM FOR CHILDREN**

AGENCY FORM NUMBER(S): None

ACTION : APPROVED
OMB NO.: 0930-0171
EXPIRATION DATE: 06/30/96

BURDEN	RESPONSES	BURDEN HOURS
Previous Status	0	0
New Status	82,630	12,864
Difference	82,630	12,864
Explanation of difference		
Program Change		12,864
Adjustment		0

TERMS OF CLEARANCE:

SEE PAGE 2 FOR TERMS OF CLEARANCE

Summary

The purpose of this request is to secure Office of Management and Budget (OMB) clearance of instruments that will be used to conduct an evaluation of the Comprehensive Community Mental Health Services Program.

Severe emotional disturbances affect about 3.5 million children and their families in the United States. How to effectively provide services to these children and their families has long been debated; evidence is growing that an integrated and coordinated system of care can more fully meet the needs of this population. The Comprehensive Community Mental Health Services Program for Children with Serious Emotional Disturbances, which is administered by the Center for Mental Health Services (CMHS) within the Substance Abuse and Mental Health Services Administration, provides funds to States to support a broad array of community-based and family-centered services through the "system of care" model. Under this new program, CMHS funds 5-year grants to States and locales to expand the array and capacity of services for children with serious emotional disturbances.

This Congressionally mandated evaluation will provide important information on a major nationwide initiative serving thousands of children and their families. Results of the evaluation will be useful to a variety of organizations and individuals:

- CMHS will determine whether the initiative expanded services to children and families and whether these services were received within a culturally competent, community-based system of care that involved families as partners. CMHS will use this information to develop policies and provide guidance and technical assistance to grantees.

- Grantees will use findings from the evaluation to improve services, allocate personnel and funding effectively, shape

future program direction and help obtain funding for their portion of match of non-Federal funds.

- Children and their families will, through their input to the evaluation, provide ongoing feedback to the local grantees, which will allow the grantees to improve services and address barriers that families perceive.

- Congress will have its mandate fulfilled and know whether continued expenditures for systems of care are justified.

- Federal agencies such as the Department of Education, the Office of Juvenile Justice and Delinquency Prevention, and the Administration of Children, Youth and Families will use the evaluation results to better meet the mental health needs of this shared target population.

- Researchers will use the variety of information produced by this evaluation to examine and understand the specific ways children get better and systems are enhanced.

Meetings and discussions conducted with an expert workgroup and individual experts in the field, a literature review, and pretest visits to four operational grantees have shown that to achieve evaluation goals, a multi-method/multi-source analysis is necessary. The evaluation has been structured to capture the linkages between an enhanced system of care and the outcomes and experiences of clients, families and providers over time. Because of the complexity and scope of the issues, several types of data are proposed for collection.

- Client descriptive data will be collected to portray the children being served by the initiative including their demographic, diagnostic, and functional characteristics, and types and costs of services they received.

- Client outcome data will be collected to determine whether the system is effectively serving children and their families, including data on functional improvement, role performance, placement, family involvement and consumer satisfaction.

  System descriptive and outcome data will be collected to show how a system develops and expands to better meet the needs of the children and families served.

Clearance is being sought for the acquisition of a core data set, a set of standardized instruments, and a site visit guide that will yield the required data.

INFORMED CONSENT

The Center for Mental Health Services is conducting an evaluation of programs it has funded. The program your child receives services from is one of these. As part of the evaluation, we would like you and your child to participate in a study. As part of the study we will ask you to fill out some forms now and again six months from now. If your child continues to receive services we will ask you to fill out the same forms one year from now and then every year your child continues in the program. The study lasts for 5 years.
There are several types of information we will ask you about. These include:

- An assessment of your child's behavior and functioning
- A sense of your satisfaction with services your child and family are receiving
- A report of your feelings of empowerment in seeking and receiving services

We would also like your child to answer some questions. We are interested in finding out about the services your child receives and about how he or she changes during the time he or she is enrolled in the program. Your child's feelings about the services being received are also important to us and we will ask questions about them. The forms we are using have been used in many other studies and filled out by many different children. They are written by children and may either be read by a child or to a child.

Your input, and that of your child, is vital to our understanding of how mental health services may be helpful. If you decide to participate in the study here are some things you should know:

- Participation in this study is totally voluntary.
- Everything you write or say in this study is confidential.
- Any questions you have about this study will be answered before you or your child fills out any forms.
- Neither you nor your child have to participate in order to receive services.
- Your child's care will in no way be affected by your decision to participate in the study or by how you answer any questions.
- Nothing that will identify you or your child will be made available to researchers conducting this study.
- You may choose to stop participating in the study at any time, for whatever reason.
- You may have a copy of any report we write about the study.

- You will be given a small stipend for participating in the study in order to compensate you for the valuable time you have taken to participate.

A federal certificate of confidentiality will protect the researchers from being forced to release any study information in which you are identified, even under a court order or subpoena. Your signature below indicates that you have read this form or it has been read to you. By signing your full name below you are agreeing to participate in the study and stating that you understand the description given above.

Participant Signature _____

Witness _____

Date _____

Form Approved
OMB NO. 0930-____
Exp. Date _____

Youth Self Report

YOUTH SELF-REPORT FOR AGES 11-18

For office use only
ID #

YOUR NAME

YOUR SEX ☐ Boy ☐ Girl

YOUR AGE

ETHNIC GROUP OR RACE

TODAY'S DATE
Mo. ____ Date ____ Yr ____

YOUR BIRTHDATE
Mo. ____ Date ____ Yr ____

GRADE IN SCHOOL

NOT ATTENDING SCHOOL ☐

IF YOU ARE WORKING, STATE TYPE OF WORK

PARENTS' USUAL TYPE OF WORK, even if not working now (*Please be specific – for example, auto mechanic, high school teacher, homemaker, laborer, lathe operator, shoe salesman, army sergeant.*)

FATHER'S TYPE OF WORK _____

MOTHER'S TYPE OF WORK _____

Please fill out this form to reflect your views, even if other people might not agree. Feel free to write additional comments beside each item and in the spaces provided on pages 2 and 4

I. Please list the sports you most like to take part in. For example: swimming, baseball, skating, skate boarding, bike riding, fishing, etc.

☐ None

	Compared to others of your age, about how much time do you spend in each?			Compared to others of your age, how well do you do each one?		
	Less Than Average	Average	More Than Average	Below Average	Average	Above Average
a. _____	☐	☐	☐	☐	☐	☐
b. _____	☐	☐	☐	☐	☐	☐
c. _____	☐	☐	☐	☐	☐	☐

II. Please list your favorite hobbies, activities, and games, other than sports. For example: cards, books, piano, autos, crafts, etc. (Do **not** include listening to radio or TV.)

☐ None

	Compared to others of your age, about how much time do you spend in each?			Compared to others of your age, how well do you do each one?		
	Less Than Average	Average	More Than Average	Below Average	Average	Above Average
a. _____	☐	☐	☐	☐	☐	☐
b. _____	☐	☐	☐	☐	☐	☐
c. _____	☐	☐	☐	☐	☐	☐

III. Please list any organizations, clubs, teams or groups you belong to.

☐ None

	Compared to others of your age, how active are you in each?		
	Less Active	Average	More Active
a. _____	☐	☐	☐
b. _____	☐	☐	☐
c. _____	☐	☐	☐

IV. Please list any jobs or chores you have. For example: Paper route, babysitting, making bed, working in store, etc. (Include **both** paid and unpaid jobs and chores.)

☐ None

	Compared to others of your age, how well do you carry them out?		
	Below Average	Average	Above Average
a. _____	☐	☐	☐
b. _____	☐	☐	☐
c. _____	☐	☐	☐

U. of Vermont, 1 So. Prospect St., Burlington, VT 05401
1-91 Edition

V. 1. About how meny close friends do you have? (Do not include brothers & sisters) ☐ None ☐ 1 ☐ 2 or 3 ☐ 4 or more

2. About how many times a week do you do things with eny friends outside of regular school hours? (Do not include brothers & sisters) ☐ less than 1 ☐ 1 or 2 ☐ 3 or more

VI. Compered to others of your age, how well do you:

	Worse	About the same	Better	
a. Get along with your brothers & sisters?	☐	☐	☐	☐ I have no brothers or sisters
b. Get along with other kids?	☐	☐	☐	
c. Get along with your parents?	☐	☐	☐	
d. Do things by yourself?	☐	☐	☐	

VII. Performance in academic subjects. ☐ I do not go to school because _____

	Failing	Below Average	Average	Above Average
a. English or Language Arts	☐	☐	☐	☐
b. History or Social Studies	☐	☐	☐	☐
c. Arithmetic or Math	☐	☐	☐	☐
d. Science	☐	☐	☐	☐
Other academic subjects – for example computer courses, foreign language, business. Do *not* include gym, shop, driver's ed., etc e. _____	☐	☐	☐	☐
f. _____	☐	☐	☐	☐
g. _____	☐	☐	☐	☐

Do you have any illness, physicel disability, or handicap? ☐ No ☐ Yes – please describe

Please describe any concerns or problems you heve about school:

Please describe any other concerns you heve:

Please describe the best things about yourself:

Below is a list of items that describe kids. For each item that describes you **now** or **within the past 6 months**, please circle the **2** if the item is **very true** or **often true** of you. Circle the **1** if the item is **somewhat** or **sometimes true** of you. If the item is **not true** of you, circle the **0**.

0 = Not True 1 = Somewhat or Sometimes True 2 = Very True or Often True

0 1 2 1 I act too young for my age
0 1 2 2 I have an allergy (describe) _____
_____
_____
0 1 2 3. I argue a lot
0 1 2 4 I have asthma
0 1 2 5. I act like the opposite sex
0 1 2 6 I like animals
0 1 2 7. I brag
0 1 2 8 I have trouble concentrating or paying attention
0 1 2 9 I can't get my mind off certain thoughts (describe): _____
_____
_____
0 1 2 10. I have trouble sitting still
0 1 2 11. I'm too dependent on adults
0 1 2 12. I feel lonely
0 1 2 13. I feel confused or in a fog
0 1 2 14 I cry a lot
0 1 2 15. I am pretty honest
0 1 2 16. I am mean to others
0 1 2 17. I daydream a lot
0 1 2 18 I deliberately try to hurt or kill myself
0 1 2 19 I try to get a lot of attention
0 1 2 20 I destroy my own things
0 1 2 21 I destroy things belonging to others
0 1 2 22. I disobey my parents
0 1 2 23 I disobey at school
0 1 2 24 I don't eat as well as I should
0 1 2 25 I don't get along with other kids
0 1 2 26. I don't feel guilty after doing something I shouldn't
0 1 2 27. I am jealous of others
0 1 2 28 I am willing to help others when they need help
0 1 2 29 I am afraid of certain animals, situations, or places, other than school (describe): _____
_____
_____
0 1 2 30. I am afraid of going to school
0 1 2 31. I am afraid I might think or do something bad
0 1 2 32 I feel that I have to be perfect
0 1 2 33. I feel that no one loves me
0 1 2 34 I feel that others are out to get me
0 1 2 35. I feel worthless or inferior
0 1 2 36. I accidentally get hurt a lot
0 1 2 37. I get in many fights
0 1 2 38 I get teased a lot
0 1 2 39 I hang around with kids who get in trouble

0 1 2 40 I hear sounds or voices that other people think aren't there (describe) _____
_____
_____
0 1 2 41 I act without stopping to think
0 1 2 42 I would rather be alone than with others
0 1 2 43 I lie or cheat
0 1 2 44 I bite my fingernails
0 1 2 45 I am nervous or tense
0 1 2 46 Parts of my body twitch or make nervous movements (describe).
_____
_____
0 1 2 47 I have nightmares
0 1 2 48 I am not liked by other kids
0 1 2 49 I can do certain things better than most kids
0 1 2 50. I am too fearful or anxious
0 1 2 51 I feel dizzy
0 1 2 52 I feel too guilty
0 1 2 53. I eat too much
0 1 2 54 I feel overtired
0 1 2 55 I am overweight
56. Physical problems without known medical cause
0 1 2 a. Aches or pains (**not** headaches)
0 1 2 b. Headaches
0 1 2 c. Nausea, feel sick
0 1 2 d. Problems with eyes (describe):
_____
_____
0 1 2 e. Rashes or other skin problems
0 1 2 f. Stomachaches or cramps
0 1 2 g. Vomiting, throwing up
0 1 2 h. Other (describe): _____
_____
_____
0 1 2 57. I physically attack people
0 1 2 58 I pick my skin or other parts of my body (describe): _____
_____
_____
0 1 2 59 I can be pretty friendly
0 1 2 60 I like to try new things
0 1 2 61. My school work is poor
0 1 2 62 I am poorly coordinated or clumsy
0 1 2 63 I would rather be with older kids than with kids my own age

Please see other side

0 = Not True 1 = Somewhat or Sometimes True 2 = Very True or Often True

0 1 2 64 I would rather be with younger kids than with kids my own age
0 1 2 65. I refuse to talk
0 1 2 66 I repeat certain actions over and over (describe): _____
_____
_____
0 1 2 67. I run away from home
0 1 2 68. I scream a lot
0 1 2 69. I am secretive or keep things to myself
0 1 2 70. I see things that other people think aren't there (describe): _____
_____
_____
0 1 2 71 I am self-conscious or easily embarrassed
0 1 2 72. I set fires
0 1 2 73 I can work well with my hands
0 1 2 74 I show off or clown
0 1 2 75. I am shy
0 1 2 76 I sleep less than most kids
0 1 2 77. I sleep more than most kids during day and/or night (describe): _____
_____
_____
0 1 2 78 I have a good imagination
0 1 2 79 I have a speech problem (describe) _____
_____
_____
_____
0 1 2 80 I stand up for my rights
0 1 2 81 I steal at home
0 1 2 82 I steal from places other than home
0 1 2 83 I store up things I don't need (describe).
_____
_____
0 1 2 84 I do things other people think are strange (describe): _____
_____
_____

0 1 2 85. I have thoughts that other people would think are strange (describe): _____
_____
_____
_____
0 1 2 86 I am stubborn
0 1 2 87. My moods or feelings change suddenly
0 1 2 88. I enjoy being with other people
0 1 2 89 I am suspicious
0 1 2 90. I swear or use dirty language
0 1 2 91. I think about killing myself
0 1 2 92 I like to make others laugh
0 1 2 93 I talk too much
0 1 2 94 I tease others a lot
0 1 2 95. I have a hot temper
0 1 2 96. I think about sex too much
0 1 2 97. I threaten to hurt people
0 1 2 98. I like to help others
0 1 2 99 I am too concerned about being neat or clean
0 1 2 100 I have trouble sleeping (describe): _____
_____
_____
0 1 2 101. I cut classes or skip school
0 1 2 102. I don't have much energy
0 1 2 103 I am unhappy, sad, or depressed
0 1 2 104 I am louder than other kids
0 1 2 105. I use alcohol or drugs for nonmedical purposes (describe): _____
_____
_____
_____
0 1 2 106. I try to be fair to others
0 1 2 107. I enjoy a good joke
0 1 2 108 I like to take life easy
0 1 2 109 I try to help other people when I can
0 1 2 110. I wish I were of the opposite sex
0 1 2 111. I keep from getting involved with others
0 1 2 112. I worry a lot

Please write down anything else that describes your feelings, behavior, or interests

PLEASE BE SURE YOU HAVE ANSWERED ALL ITEMS

collection and they will be trained on strategies to maintain confidentiality. No name-linked data will be used in evaluation reports. Analysis will be done and results reported on aggregate data only.

The SAMHSA Privacy Act Coordinator has determined that the Privacy Act does not apply to this study because no identifiers will be transmitted to the national evaluator.

11. Questions of a Sensitive Nature

Because this project concerns services to seriously emotionally disturbed children and their families, it is necessary to ask questions that are of a sensitive nature. Questions will address dimensions such as client diagnosis and functioning, behaviors, school performance and involvement with the law enforcement system. The answers to these questions will determine baseline status and changes since entering the system of care. Since each grantee must keep data on client status and service use, as well as treatment plan and other information, the data collection required for the national evaluation is not introducing new, sensitive domains of inquiry, but is paralleling standard procedures in the field of children's mental health.

As stated above, children and their families who are selected to participate in the evaluation effort will give an informed consent before any questionnaires are administered. Evaluation results will not link any sensitive information to individuals.

12. Estimates of Annualized Cost

The national evaluation contract has been awarded to Macro International for a three year period. The contract award totals $4,411,235. It is estimated that one full-time CMHS employee will be involved for 60 percent of an FTE for each year of the evaluation. Assuming an average annual salary of

December 11, 1995

The Honorable Ted Stevens, Chairman
Senate Governmental Affairs Committee
340 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Stevens:

The Research and Privacy Coalition appreciated your invitation to present testimony November 9 on the Family Privacy Protection Act. In response to your letter of November 22, the Coalition has enclosed its response to questions posed by Senators Glenn and Levin.

I hope you will let me know if I can I can be of further assistance.

Sincerely,

Felice J. Levine

Felice J. Levine
Research and Privacy Coalition

Question from Senator Glenn:

Please describe how the scope and impact of H.R. 1271 differs from that of last year's Education Act amendment?

Although the purpose and much of the wording of the two bills are similar, there are three substantive differences. The major difference is the scope. The Grassley amendment applies only to research funded by the U.S. Department of Education. The conference report for the Goals 2000 bill made that explicit. H.R. 1271, in contrast, would apply to all surveys of minors, in school or out, if the research was part of a "program or activity" funded by the federal government.

A second difference between the Grassley amendment and H.R. 1271 is that the latter contains a cause of action, with no limit on the federal government's liability. The House Government Reform and Oversight Committee reported the bill with a $500 limit on liability, but that limit was stripped with passage of the Souder amendment.

The third difference is in the categories of inquiry covered by the Grassley amendment. The Grassley amendment lists "income" as a category of survey question that would trigger the requirement for written parental permission. The House Committee was persuaded by arguments from representatives of the U.S. Census Bureau and Office of Management and Budget that the great majority of U.S. surveys collect data on income, and its inclusion in the list was problematic. The House committee dropped "income," but added "religion" as a category.

The Research and Privacy Coalition supports the removal of "income" from the categories of questions that would trigger written parental permission, and has taken no position on the cause of action. The Coalition's chief concern remains the expanded scope of H.R. 1271. The Coalition was formed after passage of the Grassley amendment, though many of our members had opposed the Grassley amendment. The only reason the Grassley amendment is less onerous than H.R. 1271 is that its reach extends only to one Department.

The Research and Privacy Coalition has maintained that H.R. 1271 is unnecessary, and would in fact harm the federal government's efforts to collect important data on children at risk. Current regulations to protect human subjects in research (45 CFR 46) are adequate to allow for the privacy of parents, and to allow families who prefer that their children not be surveyed to decline. The regulations provide that written parental permission is the standard; and indeed, it must be required if federally funded research poses a greater than minimal risk to a minor. However, Institutional Review Boards (IRBs) have the authority to waive written parental permission under limited circumstances where the research poses "less than minimal risk." This flexibility includes allowing for oral parental permission when the research would indicate that is more appropriate (for example, a telephone survey). The Coalition's testimony cites studies showing the adverse impacts of a universally-applied written permission requirement.

The term "program or activity" in H.R. 1271 is problematic, because it seems to extend the requirement for written parental permission to any survey, whether federally funded or not, if the survey were given within a program or activity that receives federal funds. For example, if the National Geographic Society wanted to survey high school students about career preferences, and included questions about religious vocations, written parental permission would likely be required. This may be one way to police those maverick "school newspaper" surveys, but it would have same negative impact on privately funded studies as on federal studies. The report language in H.R. 1271 as reported from the House Government Reform and Oversight Committee clarifies that the term is meant to apply to surveys or questionnaires that are themselves federally funded, not to all federally funded programs. But use of the term "program or activity" in the bill language could lead to a broader interpretation with evident cost implications. The present bill language is ambiguous, and could lead to a broader interpretation than legislatively intended.

Question from Senator Levin:

In your testimony, you raised several cost concerns. Are there any studies that evaluate the additional costs that states and local school districts will incur as a result of enacting H.R. 1271, as it is currently worded. If there is none, how long would a cost analysis take and whom would you recommend to conduct such a study?

Let me first refer you to the enclosed March 31, 1995 memorandum from the Congressional Budget Office. The memorandum concludes:

"Summarizing the available information, the requirement of written parental consent could add nearly 50 percent to the data collection costs of some surveys directed at respondents under the age of 18. CBO estimates that, depending on the surveys administered in any particular year, requiring written parental consent would add several million dollars to the costs of federally funded surveys. In addition, non-response to the surveys as a result of the consent requirement could materially alter the usefulness of the surveys themselves."

The author of the memorandum notes that the CBO estimate of "several million dollars" is preliminary and based on a small sample of federal agencies currently sponsoring federal survey research. Given that the actual costs of an absolute written requirement could be much higher, we would urge that the Committee request that the General Accounting Office undertake a revenue estimate.

I have also enclosed a 1989 study by the Rand Corporation indicating that an absolute written consent requirement could result in staggering costs. In one study the necessary follow-up, including phone calls, home visits, and the extra time to get parents to return written consent forms, increased costs from $1 to $25 per response.

According to Rand scholar Sandra Berry, the final costs involved in implementing H.R. 1271 will depend upon its scope. For example, what kinds of data collection efforts are covered (topics, etc.), in what populations (school-based surveys only, any federally funded survey of minors, etc.), and under what sponsorship (contract, grant, state or local departments). The practical costs of implementing any kind of consent procedure include:

- Need to verify parent/guardian names and addresses;
- Preparing informed consent materials for mailing and/or distribution to students;
- Time to work with schools on distribution and processing responses; and
- Telephone calls and special mailings to follow up with non-responses.

These costs apply differentially, depending on whether consent is written or not, and on conditions at the schools (mobility of students, quality of address lists, etc.). Additional costs of

written consent procedures also include scheduling constraints for carrying out data collection on a school calendar and, of course, the problem of biased nonresponse.

In order to estimate these costs overall, one would need to collect some information on how many data collection efforts might fall under the scope of the legislation and make some assumptions about comparative costs, based on other data collection for which cost information was collected.

We must point out that if the federal government, as the sponsor of research, does not take on the additional costs that would be incurred with passage of this legislation, the research will likely not be done at all. Schools and school districts can hardly be expected to use their own resources to follow up with parents. Generally schools and school districts cooperate with researchers as a courtesy, and because they understand that good data on children at risk is worthwhile to have.

Not all research on children is conducted in school-based settings. If H.R. 1271 is approved, surveys of children and youth conducted in other venues would be even more difficult to conduct. For example, the cost for obtaining written parental consent (in contrast to informed consent) in a telephone survey on a national sample of youth would be enormous.

The largest costs from the legislation will be to the American public, which will be deprived of critical social science research. It is, of course, impossible to put a price tag on this lost knowledge. We urge you to seek a middle ground that reinforces privacy for families without jeopardizing critical federal data collection efforts.

This study provides new information on how passive and active consent methods work in practice. Based on results from two junior high schools, we found that (1) almost all parents received consent packages sent by regular first-class mail, but getting them to pay attention to the materials often required additional communication methods, (2) nonresponse to passive consent typically reflected conscious parental approval, (3) nonresponse to active consent generally signified latent consent, not a deliberate refusal, and (4) vigorous retrieval methods substantially raised active consent response rates, but at a high cost in time and money. These findings suggest that passive consent can provide a viable alternative to active consent when supplemented by appropriate backup and privacy safeguard measures.

AN ASSESSMENT OF ACTIVE VERSUS PASSIVE METHODS FOR OBTAINING PARENTAL CONSENT

PHYLLIS L. ELLICKSON
JENNIFER A. HAWES
The RAND Corporation

This article discusses the results of a pilot study assessing the effectiveness and costs of two methods for obtaining parental approval to conduct research with minors: active versus passive consent. The first method (active consent) involves asking all parents to return a signed consent form to indicate whether they do or do not want their child to participate in the research activities. Under active consent procedures, parents who fail to return a permission slip, as well as those individuals who indicate on the form that they do not want their child to participate in the research are treated as "parental refusals." The second

AUTHORS' NOTE: *This research was supported by a grant from the Conrad N. Hilton Foundation. The authors are grateful to Robert Bell, Sandy Berry, and Tora Bikson for helpful comments on the article, and to Diane O'Rourke for assistance with a review of the research literature on parental consent methods. An earlier draft of this article was presented at the 1987 Field Director Conference and the 1987 Annual Conference of the Western Psychological Association.*

EVALUATION REVIEW, Vol. 13 No. 1, February 1989 45-55

procedure (passive consent) asks parents to return a form only if they do not want their child to participate. If parents do not refuse, they are assumed to have granted permission for their child to participate in the research.

Researchers who have used active consent report that it yields unacceptably low response rates of only 50-60% and underrepresentation of important groups—Blacks, Asian Americans, low achievers, children with less well-educated parents, and those at risk for engaging in problem behavior (Kearney et al., 1983; Josephson and Rosen, 1978; Lueptow et al., 1977; Severson and Ary, 1983; Thompson, 1984). Such results limit the scientific validity and generalizability of survey research conducted with children; when the research includes an experimental design aimed at evaluating school-based drug prevention programs, the problems are compounded. Substantially reduced sample sizes can make it difficult to detect all but the most powerful treatment effects, and unequal distribution of specific groups across experimental conditions can produce false positive or negative effects (Biglan and Ary, 1985).

Because of its potential for severely reducing sample size and increasing sample bias, many researchers have replaced active with passive consent methods (Biglan et al., 1987; Murray et al., 1987). However, thoughtful observers disagree about whether passive consent procedures adequately fulfill requirements for obtaining informed parental consent. Some researchers argue that passive consent does not fully inform parents about the research or give them sufficient opportunity to refuse participation. Others question the underlying assumption that parents who fail to send in a refusal form have received the notice and consciously decided that their child should participate in the research. They interpret the bias toward nonresponse in "at-risk" groups as reflecting parental concerns that these children are more likely to be jeopardized by the research, particularly if confidentiality safeguards against disclosure of sensitive information are not adequately enforced.

In contrast, critics of active consent believe it requires overly stringent informed consent procedures, especially when applied to programs that offer substantial benefits, implement rigorous data safeguards, and pose minimal risk to students. They argue that carefully designed passive consent methods can avoid the negative consequences of active consent while ensuring that parents receive the consent materials, pay attention to them, and have sufficient time to refuse participation. They also believe that failure to return a signed active consent form is more likely to reflect apathy or inertia than objection to the research.

To date, however, the debate has been carried on in the absence of evidence about the meaning of parental nonresponse under either method, the effectiveness of passive consent at informing parents about the research, or the potential for raising response rates by vigorously pursuing active consent. Based on experience in two junior high schools, this study addresses those issues.

STUDY QUESTIONS AND BACKGROUND

Undertaken before launching a multiyear smoking and drug prevention experiment in 30 West Coast schools, the pilot test sought information about the following questions: (1) Can active consent response rates be substantially increased by implementing rigorous retrieval methods? At what cost? (2) Is parental nonresponse to active consent more likely to indicate apathy or a deliberate refusal? (3) Does parental nonresponse to passive consent indicate a deliberate decision to permit the child to participate in the research? (4) How effective is regular first-class mail at informing parents? The data were collected in response to a request from Rand's Human Subjects Protection Committee (HSPC), which would then use the results to inform its deliberations about approving active or passive consent for the large-scale project.

In addition to providing consent data, the pilot test was the primary vehicle for learning how well the curriculum and data collection procedures worked before implementing them in the 30 experimental schools (Ellickson, 1984a, 1984b). Hence, rather than match the two pilot schools on key population characteristics, we selected schools that would best represent the range of experience and backgrounds that the main study's survey respondents were likely to demonstrate. Together, the pilot schools provided a reasonable cross section of the school environments and student backgrounds present in the main study sample. One pilot school, located in an urban section of Los Angeles County, had a more heterogeneous, ethnically diverse student population (34% minority), the other pilot school, located on the suburban fringes of that area, had a more homogeneous, predominantly white student body (14% minority).

We employed active consent procedures in the more homogeneous suburban school because officials there had expressed concern about whether passive consent methods would adequately inform parents about the research. The second school, with more minority students, offered the potential for assessing reactions to passive consent among

those parents who the HSPC believed might be particularly concerned about protecting data privacy.

The demographic differences between the two schools, as well as the age of the students involved (grade 7) and the nature of the research program, could have affected the schoolwide consent rates reported here. We particularly urge caution in drawing comparisons between the two schools. However, our most important findings rest on analyses of data gathered from parents *within* one school at a time, where the issue of between school comparisons does not arise. These results, while clearly not generalizable to all school environments, provide important new information for evaluating the two major approaches to seeking parental consent.

OBTAINING PARENTAL CONSENT

In March of 1984 we contacted the parents of 200 seventh graders at the two schools to obtain permission for including their children in the project's pilot phase. Students in the two schools were asked to provide one or more physiological samples (saliva, urine, or hair) and fill out self-administered questionnaires describing their drug use and related attitudes and behaviors.

To maximize the likelihood that parents would receive and carefully review both the passive and active consent forms, we implemented a three-stage strategy for delivering consent materials. That strategy used both mail and school channels of communication: (1) the first consent package (containing a letter describing the prevention program and research procedures, a parent fact sheet providing additional details, and a consent form) was sent directly to the parents' homes via regular first-class mail; (2) about one week after the initial mail out, a postcard reminder was sent to all parents; and (3) about three weeks after the initial mail out, all students were asked to take an additional packet home to their parents.

Several methods were used to direct parents' attention to the consent form—sending it with an introductory letter from the school principal, stamping the message IMPORTANT INFORMATION on the envelope, and translating the materials into Spanish for the district that normally uses Spanish translation. Parents could communicate their wishes by returning the form in a postage paid preaddressed envelope, calling us collect, or contacting the school directly. To allow sufficient time for parents to respond, materials were mailed to parents about four weeks before the start of the pilot data collection.

PILOT RESULTS

Overall, 90% of all parents gave permission for their child to participate in the data collection process—86% in the active consent school and 93% in the passive consent school. However, while the 86% rate for active consent is considerably higher than that typically reported in the literature, achieving it required an intensive and costly campaign.

HOW MUCH EFFORT DOES ACTIVE CONSENT INVOLVE?

That campaign involved multiple follow-ups and several different techniques for contacting parents. Besides the postcard reminder and packet distribution to students in both schools, follow-up efforts included two telephone reminder calls to all nonrespondents, two special parent meetings, and daily teacher requests for students to return missing consent forms before the program start date.

These efforts proved quite successful. Two weeks after the initial mail out and one week after the postcard reminder, only 40% of the active consent parents had returned a permission slip, a result that parallels the experience of other studies using active consent. By the end of the fourth week, we had obtained forms from *all* 86 parents, including 12 who refused consent. As Table 1 shows, the first telephone call increased the form return rate by 14%, while the second consent package (sent home with the student) yielded an additional 21%. Bringing in the last 26% required a second round of telephone calls and daily teacher reminders asking students to remind parents to return the missing forms.

This experience resembles that reported in the mail survey research literature, which suggests that multiple follow-ups using varied techniques is the most effective way to ensure high response rates to mail solicitations (Dillman, 1978; Heberlein and Baumgartner, 1978, Baumgartner and Heberlein, 1984). However, few studies are likely to have the resources or time required to implement such extensive and costly procedures for obtaining parental consent. Our two stages of telephone follow-up alone cost approximately $25 per case. In a large study, that expense would be prohibitive. For example, calling parents for a sample of 7,500 students with an initial parental nonresponse rate of 60% would cost $112,500 (4,500 parents × $25). Conducting those calls would take about 234 interviewer days (25 minutes per case for all calls to complete), requiring a minimum period of three to four weeks for a telephone center with 20 interviewer stations. In our case, such a lengthy consent process would also have delayed data collection until

TABLE 1
Follow-Up Results for Active Consent Parents

Type and Timing of Follow-Up	*Forms Returned By*	*N*	*%*
postcard reminder (day 7)	day 14	34	39.5
first phone call to nonrespondents (day 15-17)	day 20	12	14.0
second packet via students (day 20)	day 22	18	20.9
second phone call and daily teacher reminders (day 22-25)	day 28	22	25.6
		86	100

TABLE 2
Consent Rates Under Active and Passive Consent

	Active Consent				*Passive Consent*[a]	
	No		*Yes*		*No*	
When Form Received	*N*	*%*	*N*	*%*	*N*	*%*
Before follow-up	5	5.8	29	33.7	4	3.4
After follow-up	7	8.2	45	52.3	4	3.4
Total	12	14.0	74	86.0	8	6.8

a. Total number of parents equals 117, of which 93.2% gave passive consent

well into November, precluding the acquisition of baseline data before delivery of the prevention curriculum.

WHAT DOES PARENTAL NONRESPONSE TO ACTIVE CONSENT MEAN?

As Table 2 shows, the intensive follow-up effort for active consent parents also raised the overall consent rate, from only 34% before the campaign began to 86% when it concluded. Clearly this group of parents—52% of the total who consented and 87% of the initial nonrespondents—had not intended to object to their child's participation by failing to return a signed form. While they ultimately approved their child's inclusion in the evaluation, they lacked motivation to sign and return the form without considerable prompting. Moreover, of the 14% who refused permission, almost half registered their veto *before* the telephone and school follow-up began. Hence, nonresponse signaled a latent refusal for only 8% of the active consent parents. For the great majority, failure to send in a form appeared to reflect latent consent combined with apathy or inertia.

DOES PARENTAL NONRESPONSE TO PASSIVE CONSENT SIGNIFY CONSENT?

While nonresponse to the active consent procedure was considerably more likely to reflect "apathetic consent" than a deliberate refusal, nonresponse to passive consent typically reflected a conscious parental decision to allow the child to participate in the research. As Table 2 shows, 8 of the 117 parents (7%) in the passive consent school eventually sent in signed forms refusing permission for the child to participate. However, only 4 of those refusals were received within two weeks of the mail out. Thus we called the remaining 113 parents to ascertain whether they had received the consent materials and understood what the data collection entailed. We reached 94 of them.

Those calls triggered only 4 more refusals, indicating that equating nonresponse with permission accurately reflected the wishes of 96% of the parents reached by phone. Moreover, in response to a structured set of questions, the great majority of those parents (87%) specifically said that they had received the materials, understood them, and decided to allow their child to participate.

Overall, therefore, the pilot procedures suggest that failure to return a form is considerably more likely to reflect latent consent than latent refusal. These findings apply no matter what the request—for a signed slip from every parent or for a signed slip only from those who object to their child's participation in the research.

DID PARENTS RECEIVE AND PAY ATTENTION TO PASSIVE CONSENT MATERIALS?

But did passive consent satisfactorily inform parents about the research? Regular first-class mail appeared to ensure parental receipt of the consent package in almost all cases. No packets were returned to participating schools as undeliverable and, as noted earlier, 87% of the passive consent parents contacted said they had received and understood

the consent materials. Of the 13% who indicated they did not remember getting a copy of the letter, all but one gave the same address provided by the school. These figures suggest that the original package was probably delivered, but that parents either misplaced it or failed to read the materials carefully.

Nevertheless, the 13% who did not remember getting a copy of the letter concerned us. All but one of these parents apparently had received the consent package but had not paid attention to it, despite our efforts to enhance its external importance and internal readability. Hence, we concluded that responsible use of passive consent requires special efforts to make sure parents both receive the consent materials and *pay attention* to it. Using different channels of communication (delivery through the school as well as by mail) is one way to do this: as the results from the active consent school showed, sending the consent packet home with students stimulated a response from a substantial proportion of parents who had ignored materials received by mail.

SUMMARY

Because each research project encompasses different substantive issues, subjects, and procedures, deciding whether passive or active consent is appropriate must proceed on a case-by-case basis. This study provides data about the effectiveness and costs of each method that should help interested parties make more informed decisions. Overall, it suggests that carefully designed passive consent procedures can inform parents while avoiding the large nonresponse rates and sample bias often associated with active consent procedures. As in other studies, active consent initially yielded an unacceptably low response rate. Raising the rate to 100% required extensive follow-up efforts that would be prohibitively expensive and time consuming for large research projects. Moreover, that effort secured few additional parent refusals, indicating that nonresponse was considerably more likely to signify latent consent than a deliberate refusal.

The pilot also showed that passive consent procedures, appropriately designed and implemented, could minimize the likelihood that parents might not receive the consent materials and improve the likelihood that they would be read. No mailings were returned as undeliverable in either school, and only one address required updating. Sending materials home with the child provided an effective backup method for getting the attention of parents who ignore mail solicitations. In addition, equating nonresponse with permission appeared to reflect the true preferences of most parents in the passive consent school. Of the 94 parents contacted by phone, the great majority said they had received the consent package and intended their lack of response to communicate approval of their child's participation in the research. Only 4 subsequently refused permission.

Based on these findings, we recommended implementing a modified form of passive consent that would provide backup procedures for reaching parents who might not pay attention to mail solicitations. The committee approved a three-stage process that uses both mail and school channels.

DISCUSSION

Because disclosure of sensitive individual information constitutes the major risk to students who participate in drug use research, researchers need to promise confidentiality *and* deliver on that promise, whichever consent procedure they use. This guarantee has a heightened ethical dimension under passive consent, whereby the researcher takes on the added risk of mistaking nonresponse for consent and possibly exposing students to risks that their parents have not explicitly accepted. While this study suggests that the risk of falsely assuming consent is small, it does not suggest that either it or the risk of disclosure should be ignored

The risk of mistaking nonresponse for consent can be reduced by procedures designed to increase the likelihood that parents will receive consent materials, pay attention to them, and have sufficient time to respond. Besides using multiple methods to reach parents (regular mail plus school follow-up), we found it effective to make the materials as clear and easily understood as possible, translating them when appropriate, and highlighting their importance by including a letter from the school principal and attention-getting markings on the envelope. We also allowed parents four weeks to respond. The efficacy of these procedures is underscored by our subsequent experience with over 9,500 students from eight California and Oregon school districts. During four separate waves of data collection, only one parent complained that he had not known about the research or received the consent materials.

Minimizing the risk of disclosure requires careful data safeguards in the field and at the research institution. Most important is the need to prevent the association of an individual child's name with sensitive information. Following typical practice, we kept participant names separate from their survey responses and stored the link between names

and survey IDs in a locked facility accessible only to authorized staff. When collecting data in the schools, we found it essential to restrict data collection and handling to specially trained staff, to prevent school officials or visitors from seeing student responses, and to remove all data from the school expeditiously. Because we asked about student drug use, we also applied for a Department of Health and Human Services (DHHS) confidentiality certificate that guarantees that individual data will be protected from subpoena. Four successful waves of data collection without a single violation of data privacy have supported the efficacy of these procedures as well.

Our experience suggests that passive consent, when supplemented by appropriate backup and safeguard measures, can provide a feasible and ethical alternative to active consent. Nevertheless, such decisions should not be taken lightly. To enable scientific advance without disservice to individual rights, researchers must carefully weigh the pros and cons of active versus passive consent procedures for each individual project.

REFERENCES

BAUMGARTNER, R. and T. A. HEBERLEIN (1984) "Recent research on mailed questionnaire response rates," pp. 65-76 in D C. Lockhart (ed.) Making Effective Use of Mailed Questionnaires. New Directions for Program Evaluation, No. 21. San Francisco: Jossey-Bass.

BECK, S. et al. (1984) "A comparison of children who receive and who do not receive permission to participate in research." J. of Abnormal Psychology 12 (4) 573-580.

BIGLAN, A. and D. ARY (1985) "Methodological issues in research on smoking prevention." NIDA Research Monograph #63: 170-195.

BIGLAN, A., H. H. SEVERSON, D. V. ARY, C. FALLER, C. GALLISON, R THOMPSON, R. GLASGOW, and E. LICHTENSTEIN (1987) "Do smoking prevention programs really work? Attrition and the internal and external validity of an evaluation of a refusal skills program." J. of Behavioral Medicine 10 (2) 159-171.

DILLMAN, D. A. (1978) Mail and Telephone Surveys New York: Wiley-Interscience.

ELLICKSON, P. L. (1984a) Project ALERT: A Smoking and Drug Prevention Experiment, First Year Progress Report, No. N-2184-CHF. Santa Monica, CA: Rand.

ELLICKSON, P. L. (1984b) Designing an Effective Prevention Program: Principles Underlying the RAND Smoking and Drug Prevention Experiment, No. P-7068-CHF. Santa Monica, CA: Rand.

HEBERLEIN, T. A. and R. BAUMGARTNER (1978) "Factors affecting response rates to mailed questionnaires: a quantitative review of the published literature." Amer. Soc. Rev. 43. 447-462.

JOSEPHSON, E. and M. A. ROSEN (1978) "Panel loss in a high school study," in D. Kandel (ed.) Longitudinal Research on Drug Use, Empirical Findings and Methodological Issues. Washington, DC: Hemisphere.

KEARNEY, K. et al. (1983) "Sample bias resulting from a requirement for written parental consent." Public Opinion Q 47. 96-102.

LUEPTOW, L. et al. (1977) "The impact of informed consent regulations on response rate and response bias." Social Methods and Research 6 (2). 183-204.

MURRAY, D. M., C M O'CONNELL, L. A. SCHMID, and C. L. PERRY (1987) "The validity of smoking self-reports by adolescents: a reexamination of the bogus pipeline procedure." Addictive Behaviors 12: 7-15

SEVERSON, H. and D. ARY (1983) "Sampling bias due to consent procedures with adolescents" Addictive Behaviors 8. 433-437.

THOMPSON, T (1984) "A comparison of methods of increasing parental consent rates in social research." Public Opinion Q 48. 779-787.

Phyllis L. Ellickson is a Senior Behavioral Scientist in the Behavioral Science Department at the RAND Corporation.

Jennifer A. Hawes is an Associate Survey Analyst in the Behavioral Science Department at the RAND Corporation.

The University of Michigan

MONITORING THE FUTURE PROGRAM • SURVEY RESEARCH CENTER
INSTITUTE FOR SOCIAL RESEARCH • ANN ARBOR, MI 48106-1248
TELEPHONE: 313/763-5043
800/766-2864
FAX: 313/936-0043

November 28, 1995

The Honorable Ted Stevens, Chairman
Committee on Governmental Affairs
United States Senate
Washington, DC 20610-6250

Dear Senator Stevens:

Re: The Committee on Governmental Affairs' hearing on HR 1271, the Family Privacy Protection Act, held November 9, 1995.

Thank you for providing the post-hearing questions from Senator Levin regarding my testimony at the November 9th hearings. The questions, along with my answers to them, are enclosed.

I remain hopeful that your Committee can see a way to serve the legitimate interests of parents with regard to advance notification and description of forthcoming surveys, along with an easy means for them to decline, without destroying the substantial corpus of research which sheds light on the scale and nature of the problems our young people are experiencing. We all need the understanding generated by this work--parents and policy-makers most of all.

Please let me know if there is any way that I could be of further assistance to the Committee, and thank you again for the opportunity to testify.

Best regards,

Lloyd D. Johnston, Ph.D.
Program Director

LDJ:jrb

Post-Hearing Questions of Senator Levin
Response from Dr. Lloyd Johnston

1. *How many children have been surveyed by the Michigan Survey Research Center over the last 20 years?*

Over the 21 years of the study's existence we have surveyed approximately one-half million students. For 21 years we have surveyed approximately 17,000 high school seniors per year, and since 1991 approximately 32,000 8th and 10th grade students yearly, as well. The annual survey at present contains approximately 50,000 8th, 10th, and 12th grade students combined, located in about 420 public and private schools in the United States. All of these samples are nationally representative.

2. *How many times has the center been sued by a parent for causing harm to a child? Is this a big problem for the research field in general?*

Over the 21-year life of the study we have never been sued by a parent for any reason, and I am not aware of any case in which the parent of a student sued an investigator conducting any survey involving minors which was supported by a Federal grant or contract. This undoubtably is because virtually all such research efforts already must pass through a rigorous review for the treatment of human subjects, including reviews by (a) a committee of peers which conducts the funding review for the Federal agency; (b) the Institutional Review Board at the institution proposing to conduct the research; (c) the review staff of the Federal agency sponsoring the research; and (d) in the case of school-based surveys, very often the school district's review committee.

○

ISBN 0-16-054160-3
9 780160 541605 90000